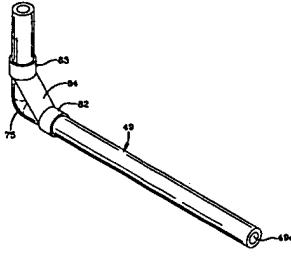


(51) International Patent Classification 6 : F16K 7/02 // A61M 39/12	A1	(11) International Publication Number: WO 97/11296
		(43) International Publication Date: 27 March 1997 (27.03.97)
(21) International Application Number: PCT/US96/14602		(74) Agent: WOODWORTH, Brian, R. et al.; Abbott Laboratories, CHAD 0377/APG-2, 100 Abbott Park Road, Abbott Park, IL, 60064-3500 (US).
(22) International Filing Date: 11 September 1996 (11.09.96)		
(30) Priority Data: 532,020 21 September 1995 (21.09.95) US		(81) Designated States: AU, BR, CA, JP, MX, NZ, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(71) Applicant: ABBOTT LABORATORIES (US/US); CHAD 0377/APG-2, 100 Abbott Park Road, Abbott Park, IL, 60064-3500 (US).		
(72) Inventor: OSBORNE, Robert, S.; 227 Brookhill Drive, Columbus, OH 43220 (US); PHONTEK, Carl, J.; 118 Beech Ridge Drive, Powell, OH 43065 (US); BUCK, Bradford, L.; 3710 Peak Ridge Drive, Columbus, OH 43230 (US); FLEMING, Matthew, S.; 3970 Mountainview Road, Columbus, OH 43220 (US); MCGREGOR, Grant, R.; 1046 South Avenue, Columbus, OH 43228 (US); PATTON, William, E.; 5757 Adie Court, Dublin, OH 43017 (US); ALEXANDER, Kathryn, E.; 265 Oakline Park Drive, Columbus, OH 43214 (US); HARRIS, Jeremy, M.; 476 Park Overlook, Worthington, OH 43201 (US); LYON, William, F.; 1449 State Route 61, Mershon, OH 43334 (US).		
		(Published With international search report.)

(54) Title: TENSION RESPONSIVE PINCH VALVE



## (55) Abstract

A tension responsive pinch valve is made up of a combination of an elastically flexible pinch valve element and a length of flexible tubing having a section that is to be closed automatically by being distorted to the point of pinching or kinking as the tubing is bent when the distorted section is not under longitudinal tension. The pinch valve element is attached automatically with the tubing section and preferably has two end portions connected by a shank portion. The end portions are attached to the tubing section at spaced-apart points and the length of the shank portion is much longer than the shank portion of the pinch valve element. If the elastic yield strength of the shank portion is greater than the bend resistance of the flexible tubing, the encompassed section of the flexible tubing will be bent over to the point of occlusion when the section is not under tension but will allow the passage of fluid when longitudinal unkinking tension is applied.

## FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	America	GB	United Kingdom	MW	Macao
AT	Austria	GE	Georgia	MZ	Macao
AU	Australia	CG	Colombia	MZ	Macao
BE	Belgium	CI	China	MU	Macao
BR	Brazil	CO	Costa Rica	MO	Monaco
DE	Germany	CR	Croatia	MV	Macao
DK	Denmark	CU	Cuba	MZ	Macao
ES	Spain	DK	Dominican Republic	NC	New Caledonia
FI	Finland	DO	Dominican Republic	NE	Negev
FR	France	DK	Dominican Republic	NG	Ngaparou
DE	Germany	DO	Dominican Republic	NI	Negev
GR	Greece	DK	Dominican Republic	NO	Negev
HK	Hong Kong	DO	Dominican Republic	NP	Negev
IE	Ireland	DK	Dominican Republic	NR	Negev
IL	Israel	DO	Dominican Republic	NU	Negev
IN	India	DK	Dominican Republic	OM	Negev
IS	Iceland	DO	Dominican Republic	PA	Negev
IT	Italy	DK	Dominican Republic	PE	Negev
JP	Japan	DO	Dominican Republic	PT	Portugal
KR	Korea	DK	Dominican Republic	PT	Portugal
LT	Lithuania	DO	Dominican Republic	RO	Romania
LU	Luxembourg	DK	Dominican Republic	RU	Russia, Federation
LV	Lvonia	DO	Dominican Republic	SD	Sabah
MC	Monaco	DK	Dominican Republic	SE	Sweden
MD	Moldova	DO	Dominican Republic	SG	Singapore
MX	Mexico	DK	Dominican Republic	SI	Slovenia
NL	Netherlands	DO	Dominican Republic	SK	Slovakia
NO	Norway	DK	Dominican Republic	SV	Sierra Leone
NZ	New Zealand	DO	Dominican Republic	TD	Chad
NO	Norway	DK	Dominican Republic	TH	Thailand
PT	Portugal	DO	Dominican Republic	TI	Tajikistan
RO	Romania	DK	Dominican Republic	TT	Tobago and Tabaigua
RU	Russia, Federation	DO	Dominican Republic	UA	Ukraine
SD	Sabah	DK	Dominican Republic	US	United States
SE	Sweden	DO	Dominican Republic	US	United States of America
SG	Singapore	DK	Dominican Republic	UZ	Uzbekistan
SI	Slovenia	DO	Dominican Republic	VN	Vietnam
SK	Slovakia	DK	Dominican Republic		
SV	Sierra Leone	DO	Dominican Republic		
TD	Chad	DK	Dominican Republic		
TH	Thailand	DO	Dominican Republic		
TI	Tajikistan	DK	Dominican Republic		
TT	Tobago and Tabaigua	DO	Dominican Republic		
UA	Ukraine	DK	Dominican Republic		
US	United States	DO	Dominican Republic		
UZ	Uzbekistan	DK	Dominican Republic		
VN	Vietnam	DO	Dominican Republic		

WO 97/11296

PCT/US96/14602

WO 97/11296

PCT/US96/14602

2

it is very important that flow of the fluid is regulated. If the fluid delivery set employed with the peristaltic pump should be accidentally dislodged from the pump housing so that the pump rotor does not regulate fluid flow it would be very desirable to have some means that will automatically shut off the flow of fluid until the problem is observed and the fluid delivery set re-installed.

Various valve mechanisms have been employed to control the flow of air as well as of liquids, but it appears that no simple, inexpensive valves have been devised heretofore that are suited for use in a setting where it is important to have continuing regulated flow of liquid but automatic shut-off if the flow should become un-regulated. In the case of the fluid delivery sets used to administer enteral or parenteral fluids into the body of a patient, the cost of any such precautionary valve is an important consideration as the sets are used only once and discarded.

U.S. Patent 2,444,449 discloses a valving arrangement for the inflation of breath-inflatable containers such as life preservers and air cushions which have a soft rubber valve stem that is adapted to be folded on itself to retain air in the container. Two elastic members are each attached by a respective band to the base and to the free end of the valve stem at spaced apart fastening locations, with the elastic members brought together by a "keeper" at about the mid-length

10 In a number of situations it would be desirable to have a simple, inexpensive valve that will close the lumen of a flexible tube or hose automatically so that a flow of liquid through the tube or hose, usually under low or moderate pressure, will be stopped when some predetermined condition occurs until further flow is desired, yet have renewed flow easily attained. For example, in administering an enteral or parenteral fluid to a patient with a rotary peristaltic pump

20 preservers and air cushions which have a soft rubber valve stem that is adapted to be folded on itself to retain air in the container. Two elastic members are each attached by a respective band to the base and to the free end of the valve stem at spaced apart fastening locations, with the elastic members brought together by a "keeper" at about the mid-length

TENSION RESPONSIVE PINCH VALVE

## FIELD OF THE INVENTION

The invention generally relates to valves that will automatically close the lumen of flexible tubing or hoses and are tension responsive, opening only when the valve section of the tubing or hose is under sufficient longitudinal tension and closing when the tension is not being applied. The invention relates more specifically to such valves that pinch or kink the flexible tubing or hose shut to achieve a valving effect.

BACKGROUND OF THE INVENTION

15 In a number of situations it would be desirable to have a simple, inexpensive valve that will close the lumen of a flexible tube or hose automatically so that a flow of liquid through the tube or hose, usually under low or moderate pressure, will be stopped when some predetermined condition occurs until further flow is desired, yet have renewed flow easily attained. For example, in administering an enteral or parenteral fluid to a patient with a rotary peristaltic pump

of the valve stem. By proper selection of the material of which the valve stem is formed, and of elastic members with an appropriate level of elastic yield strength, the valve stem will be capable of standing erect unsided against the pull of the elastic members, once it is straightened out with some compressive squeezes to remove the kink. When it is desired to close the valve stem it is simply bent over manually and the elastic members will keep it bent. Thus, it can be seen that this valving device does not provide for continuous regulated flow of liquid through a flexible tubing with automatic valve shut-off if the flow of liquid should become unregulated.

U.S. Patent 2,002,835 discloses a valving arrangement for the control of the discharge of an aerified or gasified liquid from a bottle or other enclosed container from which the liquid will "siphon" when a discharge tube from the container is opened. The valving arrangement is constituted by a hollow closure element in the form of a kind of stopper for a bottle or flask. A flexible discharge tube extends upwardly from near the bottom of the bottle or flask and through the stopper and part way through an upstanding flexible hollow heavy-walled tubular extension of the stopper. The tubular extension loosely surrounds and extends beyond the end of the discharge tube. At about mid-length of the tubular extension the walls are thinner and the tubular extension readily bends over of its own weight and bends the discharge tube with it

sufficiently to pinch or kink the discharge tube shut, precluding discharge. The drooping end of the tubular extension is easily lifted manually to permit gasified liquid under pressure to discharge, and upon allowing the end to drop down again, the discharge tube is bent sufficiently to shut off liquid flow. This device, then, is not automatic in operation.

U.S. Patents 3,976,277 and 2,957,607 disclose an apparatus for dispensing liquids through a flexible tubing wherein solenoid-operated pinch tube means are used to compress the flexible tubing to control passage of liquid therethrough. The valve is not *per se* automatic, requiring mechanical means that must be activated to do the pinching.

U.S. Patent 4,063,706 discloses a pinch valve formed from a wire helix and a flexible tube for the control of liquid flow through the flexible tube. The control is done manually and the valve is not tension responsive.

U.S. Patent 4,620,564 discloses a device for regulating flow of liquid through a tube by twisting the tubing mechanically, the tube actually having formed therein a plurality of substantially parallel flow passages that close off as the tube is twisted. The operation is not responsive to either flow rate or longitudinal tension on the tube.

British patents 16,321; 634,975; and 1,149,915 disclose valves for closures of tubes or other structures with the

twisting of the tube mechanically or of an iris kind of mechanism like a camera aperture control.

U.S. Patents 3,995,780; 2,555,490; 4,109,486; 2,117,071; and 5,072,855 each disclose some form of pressure responsive valve controlling discharge of a slurry or paste from some kind of vessel or collapsible tube upon mechanically applied pressure or in some cases pressure manually applied.

#### SUMMARY OF THE INVENTION

The tension responsive pinch valve of the invention is made up of a combination of an elastically flexible valve element and a length of flexible tubing having a section that is to be closed, i.e., occluded, by being twisted, bent or doubled over or otherwise deformed automatically to the point of kinking or pinching shut the lumen of the tubing when the valve is not under tension. The valve element is associated with the section of the length of flexible tubing that is to be closed when not under tension.

In a preferred embodiment the valve element is attached to the exterior surface of the section of flexible tubing and has end portions connected by a middle portion in the form of a shank portion. The end portions are attached to the flexible tubing at spaced apart points longitudinally of the section such that the length of the section encompassed between the spaced apart points is much longer than the shank portion of the valve element and of an appropriate length to bend or

twist sharply and pinch shut the tubing when the end portions of the valve elements are pulled mutually closer by the shank portion when the tubing is not under tension. Under tension the shank portion is stretched and the tubing is unpinched or unkinked enough to permit passage of fluid.

There is provided in accordance with one aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and section to be reversibly closed as a valve; the pinch valve element being fixedly associated longitudinally with the section of the length of flexible tubing and capable of distorting the section to the point of pinching the lumen of the section shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element comprising an elastic, flexible polymeric material and having a pair of tubular segment end portions joined by a shank

7

portion, the tubular segment end portions being telescopically assembled with the flexible tubing and the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

10 There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element comprising an elastic, flexible polymeric material and having a rectangular substantially planar shank portion connecting rectangular substantially planar end portions each of which has a concave surface adapted to fit conformingly against an outer cylindrical surface of the flexible tubing and is bonded thereto, the pinch valve being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo

5 8

the distortion of the section of flexible tubing.

There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element comprising an elastic, flexible polymeric material and being formed in the shape of the capital letter "I" from a flat sheet, the end portions of the "I" being wrapped substantially around the flexible tubing and bonded thereto, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

15 10 There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element comprising an elastic, flexible polymeric material and having arcuate end portions that are joined by a shank portion having an arcuate cross section, the end portions each having a

9

concave surface that is mated with and bonded to the outer surface of the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

10 15 There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element being a hemi-cylindrical sleeve shaped piece of an elastic, flexible polymeric material, each end of the pinch valve element being attached to the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

20 25 There is provided in accordance with another aspect of

5 10

the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element comprising an elastic, flexible polymeric material with the pinch valve element having a pair of tubular segment end portions joined by a shank portion, one of the end portions being insert molded around the flexible tubing and the other end portion being telescopically emplaced around the flexible tubing and spaced apart from the first end portion by a positioning collar which is insert molded around the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

15 20 There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element comprising an elastic, flexible polymeric material and having a pair of closed loop end portions joined by a shank portion,

11

each end portion being telescopically emplaced around the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

10 There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element being a sharply bent piece of a highly elastic springy material molded into the wall of the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

15 There is provided in accordance with another aspect of the invention a tension responsive pinch valve comprising: an

12

assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve; the pinch valve element being a sharply bent piece of a highly elastic springy material bonded to the exterior of the wall of the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

BRIEF DESCRIPTION OF THE DRAWINGS

15 Fig. 1 is a perspective view of a pinch valve according to the invention consisting of an elastic pinch valve element together with a length of flexible tubing on which the valve element has been installed;

20 Fig. 2 is a perspective view of the pinch valve element of Fig. 1;

25 Fig. 3 is a side view of a length of flexible tubing and a flexible pinch valve element to be telescopically assembled therewith to make a pinch valve, with portions of the flexible tubing and pinch valve element identified to illustrate relative dimensions;

13

Fig. 4 is a side view of a pinch valve made from the components shown in Fig. 3;

5 Fig. 5 is a view in front elevation of a rotary peristaltic pump and fluid delivery set assembled together with a flexible pinch valve element telescopically installed on the flexible tubing of the fluid delivery set adjacent the pump rotor to make a pinch valve according to the invention, the fluid delivery set being connected at the inlet end thereof to a supply container of liquid enteral nutritional product and at the discharge end thereof to a feeding tube extending into the stomach of a patient whose abdomen is shown in fragmentary view, partly broken away and in section;

10 Fig. 6 is a perspective view of a fluid delivery set for enteral or parenteral administration of a fluid using a rotary peristaltic pump, there being a pinch valve according to the invention installed on the flexible tubing of the fluid delivery set with the valve closed in the absence of tension on the flexible tubing;

15 Fig. 7 is a side view of the fluid delivery set of Fig. 5 with tension on the flexible tubing whereby the pinch valve is open;

20 Fig. 8 is a view in front elevation of the peristaltic pump and fluid delivery set combination of Fig. 7 having a pinch valve adjacent the pump rotor and with parts of the flexible tubing of the fluid delivery set truncated and

14

foreshortened;

Fig. 9 is a perspective view of the peristaltic pump and fluid delivery set combination of Fig. 8;

5 Fig. 10 is a fragmentary view of a hanging supply container for an enteral or parenteral fluid shown connected to the inlet end of a fluid delivery set assembled with a prior art rotary peristaltic pump, and having a pinch valve of the invention adjacent the pump rotor;

10 Figs. 11 and 12, respectively, are perspective views of a different pinch valve formed of a length of flexible tubing, and of the pinch valve element therefor, this pinch valve element not requiring telescopic assembly;

15 Figs. 13 and 14, respectively, are perspective views of a different pinch valve and the pinch valve element therefor, the pinch valve element not requiring telescopic assembly;

Fig. 15 and 16 are perspective views similar to Figs. 13 and 14, respectively, of a different pinch valve and of the pinch valve element therefor, this pinch valve element also not requiring telescopic assembly;

20 Fig. 16A is a view of the surface, of the pinch valve element seen in Fig. 16, that faces toward the flexible tubing in the assembled pinch valve of Fig. 15;

25 Figs. 17 and 18 are perspective views similar to Figs. 15 and 16, respectively, of a different pinch valve, and of the pinch valve element therefor, this pinch valve element also

not requiring telescopic assembly;

Fig. 19 is a perspective view of a length of flexible tubing having a partly assembled pinch valve made thereof with yet another form of pinch valve element and with a collar on the flexible tubing to serve as a position index or stop for the installation of the second tubular segment end portion of the pinch valve element;

Fig. 20 is a perspective view of the pinch valve of Fig. 19 fully assembled, with that part of the flexible tubing between the emplaced pinch valve element-tubular segment end portions doubled over to kink back on itself, pinching the flexible tubing shut;

Fig. 21 is a perspective view of the flexible tubing and pinch valve formed thereof depicted in Fig. 20 with the flexible tubing under sufficient longitudinal tension that the pinch valve is open to fluid flow;

Fig. 22 is a side view of another elastic pinch valve element suitable for assembly with a length of flexible tubing to form a pinch valve according to the invention;

Fig. 23 is a side view of another pinch valve made up from the valve element of Fig. 22 and a length of flexible tubing, shown truncated, with the flexible tubing not under tension and doubled over and pinched between the end portions of the pinch valve element as a result of the elastic pull of the shank portion;

Fig. 24 is a side view of a pinch valve made up using the pinch valve element of Fig. 22 and a flexible tubing, shown truncated, with the ends of the flexible tubing under tension by means not shown so that the elastic pull of the shank portion of the pinch valve element is being overcome and the flexible tubing is sufficiently straight for ready flow of liquid through the valve;

Fig. 25 is a view in section of another form of tension responsive pinch valve in which a bent spring wire capable of bending flexible tubing sufficiently for occlusion is embedded in the wall of a section of the flexible tubing;

Fig. 26 is a view in section taken along the line 26-26 of Fig. 25 showing the bent spring wire molded within the tubing wall;

Fig. 26A is a view in section similar to Fig. 26 showing another form of the spring wire type of pinch valve depicted in Fig. 25 in which the wire is molded or bonded longitudinally along the outside of the flexible tubing;

Fig. 27 is a side view of another form of pinch valve in which the pinch valve element, when suitably fixed in place on a length of flexible tubing, makes the flexible tubing twist enough for occlusion to take place when the flexible tubing is not under tension;

Fig. 28 is a perspective view of the front and side of apparatus for the assembly of the pinch valve of Figs. 1 and

Fig. 29 is a perspective view of the back and side of the assembly apparatus of Fig. 28;

Fig. 30 is a front elevation view of the assembly apparatus of Fig. 28;

Fig. 31 is very greatly enlarged fragmentary view of the portion of Fig. 30 encircled by a dashed line;

Fig. 32 is a view in vertical section of the assembly apparatus taken along the line 32-32 of Fig. 30;

Fig. 33 is an exploded perspective view of the components of an assembly apparatus, such as the apparatus of Fig. 28, with a corner of the base plate cut away for purposes of illustration;

Fig. 34 is a greatly enlarged perspective view of an ejector block which may be used as a part of a sub-assembly identified by reference character 330 in Fig. 33;

Fig. 35 is a greatly enlarged perspective view of another ejector block which may be used in a modification of the sub-assembly identified by reference character 330 in Fig. 33;

Fig. 36 is an enlarged exploded perspective view of some of the components of the sub-assembly identified by reference character 330 in Fig. 33, including the ejector block of Fig. 34;

Fig. 37 is an enlarged exploded perspective view of all the components of the subassembly identified by reference

character 330 in Fig. 33 with the components shown in Fig. 36 already assembled together;

Fig. 38 is a greatly enlarged perspective view of an "L"-shaped spreader finger element showing the guide pin extending laterally from the leg portion;

Fig. 39 is a very greatly enlarged partly exploded perspective view of the sub-assembly identified by reference character 330 in Fig. 33 in the process of being assembled;

Fig. 40 is a very greatly enlarged perspective view of the sub-assembly identified by reference character 330 in Fig. 33;

Fig. 41 is a perspective view of the reverse or inside face of the cover plate;

Fig. 42 is a perspective view of the assembly apparatus with the components of a pinch valve shown in exploded view relationship about to be assembled using the assembly apparatus;

Fig. 43 is a fragmentary perspective view of the assembly apparatus shown with a first tubular segment end portion of the pinch valve element oriented for placing over, i.e., around, the fingers of the spreader finger elements;

Fig. 44 is a view similar to Fig. 43 with the first tubular segment end portion of the pinch valve element slid onto the cluster of spreader fingers to commence the assembly process;

Fig. 45 is a view in vertical section of the assembly apparatus like that shown in Fig. 32, but with the first tubular segment end portion of the pinch valve element emplaced over the spreader fingers as in Fig. 44;

5 Fig. 46 is a perspective fragmentary view similar to Fig. 44 showing the first tubular segment end portion of the pinch valve element shown in Fig. 44 stretched open radially to receive therethrough the length of flexible tubing upon which the pinch valve element is to be telescopically assembled;

10 Fig. 47 is a fragmentary view in section of the assembly apparatus and stretched first tubular segment end portion of the pinch valve element shown in Fig. 46, and with the length of flexible tubing inserted into the apparatus over the central guide rod and through the cluster of spreader fingers;

15 Fig. 48 is a front elevation of the portion of the assembly apparatus encompassed by the cover plate at the point of the assembly process illustrated in Figs. 46 and 47;

20 Fig. 49 is a fragmentary view in section of the assembly apparatus with the first tubular segment end portion of the pinch valve element relaxed upon the length of flexible tubing and with the ejector piston moved forward;

25 Fig. 50 is a front elevation of the portion of the assembly apparatus encompassed by the cover plate at the point of the assembly process illustrated in Fig. 49;

Fig. 51 is a fragmentary perspective view of assembly

apparatus closely similar to that of Fig. 42 but adapted with a longer ejector block for the next stage of assembling a pinch valve assembly with the second tubular segment end portion of the pinch valve element oriented for placing over, i.e., around, the spreader fingers and with the leading end of the length of flexible tubing bent aside temporarily;

5 Fig. 52 is a view similar to Fig. 51 showing a further step in the next stage of manufacturing a pinch valve assembly wherein the second tubular segment end portion is being 10 emplaced on the length of flexible tubing;

Fig. 53 is a fragmentary view in section of the assembly apparatus with the tubular segment end portion of the pinch valve element stretched open and the end portion of the flexible tubing doubled over as seen in Fig. 52 and inserted 15 into the assembly apparatus over the central guide rod and through the cluster of spreader fingers

Fig. 54 is a fragmentary view in section of the assembly apparatus similar to Fig. 53, but with the second tubular segment end portion of the pinch valve element relaxed around 20 the length of flexible tubing and the ejector piston moved forward.

#### DETAILED DESCRIPTION OF THE INVENTION

For the purposes of the specification and claims a tension responsive pinch valve is understood to be the

assembly of a section of a length of flexible tubing with a pinch valve element wherein the pinch valve is capable of bending or twisting the section of flexible tubing sufficiently to close the lumen thereof to prevent the passage 5 of fluid therethrough when the section or the tubing of which it is a part is not under tension sufficient to stretch or straighten the pinch valve element.

In Figs. 1 and 4 there is depicted a preferred exemplary embodiment of a pinch valve according to the invention. The 10 pinch valve is made up from a pinch valve element, such as the pinch valve element 80 shown in Figs. 2 and 3, and a section of a length of flexible tubing 49, depicted in Figs. 1 and 4 as part of the pinch valve. The pinch valve element 80 is formed of an elastic, flexible polymeric material, such as a 15 silicone rubber, and is assembled telescopically and extends longitudinally along a section 75 of the flexible tubing 49 in making up the pinch valve.

The pinch valve element 80 is seen to have tubular 20 segment end portions 82, 83 joined by a shank portion 84. The pinch valve element 80 can be made by flattening a short piece of flexible tubing and stamping or cutting out about a half or more of the width along the longitudinal mid-section leaving a short, substantially hemi-cylindrical sleeve-shaped shank portion 84 having about one third the overall length of the 25 valve element 80, and two foreshortened tubular segment end

portions 82, 83 of about equal length. The shank portion 84 should be of about the same length as each of the tubular segment end portions 82, 83.

5 A pinch valve element, such as the pinch valve element 80, and a number of other similar non-metallic pinch valve elements of the sort herein described, is made up from a flexible, elastic polymeric material such as a silicone rubber. Other pinch valve elements are made up of springy material such as steel spring wire or a similarly springy 10 cured polymeric resin. The flexible polymeric tubing with which the pinch valve element is assembled is a tubing made of a silicone rubber or other similarly flexible polymeric material.

When the pinch valve element 80 is telescopically 15 installed on section 75 of a length of flexible tubing, such as flexible tubing 49 having an outer diameter at least as great as the inner diameter of the tubular segment end portions 82, 83, and with the tubular segment end portions positioned farther apart along the section 75 of the flexible 20 tubing than the length of the shank portion 84 by virtue of doubling over the section of tubing during assembly with the valve element, with a length ratio of about 4:1, then providing the shank portion 84 of the valve element 80 has a sufficiently great elastic yield modulus to elongate the bend 25 modulus of the flexible tubing 49, the pinch valve element 80

23

will draw up the ends of the encompassed section 75 of flexible tubing 49 and bend it over and kink it so that the tubing wall pinches together as seen in Figs. 1 and 4, blocking any fluid flow therethrough unless tension is applied 5 to straighten out the flexible tubing section 75 sufficiently to open the lumen 49a for fluid flow therethrough.

Briefly stated, a tension responsive pinch valve of the present invention is an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a 10 lumen and a section to be reversibly closed as a valve. The pinch valve element is fixedly associated longitudinally with the length of flexible tubing and is capable of distorting the length of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible 15 tubing is not under tension. However, the tension responsive pinch valve assembly allows the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

The relative lengths are very important. The encompassed 20 section of the flexible tubing must be long enough that the shank portion of the pinch valve element will exert substantial longitudinal pull between the ends of the encompassed tubing section 75, but not so long that the 25 encompassed tubing section will not bend sharply enough in the

24

middle for occlusion. If too long or too short, the encompassed tubing section will simply make a gentle loop, or form a simple arc, respectively, under the pull of the shank portion of the pinch valve element. Providing the elastic 5 yield strength of the shank portion of the pinch valve element is greater than the bend resistance of the flexible tubing, the encompassed section of the flexible tubing will be bent over to the point of occlusion when the flexible tubing is not under tension, but will allow the passage of fluid while longitudinal unkinking tension is being applied.

Referring now to Figs. 3 and 4, the pinch valve element 80 is installed on a length of flexible tubing 49 with the tubular end portions 82, 83 spaced apart a distance "C" along the flexible tubing 49 whereas the shank portion 84 assumes a 10 length very close to "D" when not under tension, the length "D" being sufficiently shorter than the length "C" to bend over and pinch the tubing shut when not under sufficient tension to stretch the shank portion 84. As an example, with a 15 flexible silicone rubber tubing of 0.33 cm. (0.131 inch) inner diameter, 0.51 cm. (0.199 inch) outer diameter and a wall thickness of about 0.086 cm. (0.034 inch), and with a pinch 20 valve 80 element die cut from the same type of tubing having the inner edges of the tubular end portions 82, 83 spaced apart by a shank portion about 0.51 cm. (0.199 inch) in length 25 when not under tension, that is to say when unstretched, the

25

inner edges of the tubular end portions 82, 83 should be separated by a distance of about 2.0 cm. (0.80 inch) when installed telescopically on the length of flexible tubing 49, in order to obtain a desired tightness of pinching or kinking 5 to block fluid flow. For a given elastically flexible tubing, the dimensions are very important to obtain the desired valve action with good opening and sufficiently positive shut off. The length of the encompassed tubing section 75 between the tubular segment end portions of the pinch valve element is 10 especially important to get sufficient doubling over for a sharp bend, but not so much as to form a looser loop. This can be determined empirically by trial and error for a given size flexible tubing made of a material with a given modulus of elasticity.

As indicated, an important use of the pinch valve of the invention is as a precaution against unregulated flow of enteral or parenteral fluid in the event of accidental or unintended dismounting of a fluid delivery set from a rotary peristaltic pump. For example, as shown in Fig. 5, a liquid 20 enteral nutritional fluid is being drawn from a hanging supply container 91 into a fluid delivery set 42 mounted on the housing 41 of a peristaltic pump and delivered to a feeding tube 69 that extends through a gastrostomy 70 into the stomach 74 of a patient.

The pinch valve element 80 seen in Figs. 6 and 7 has been

26

assembled with a length of flexible tubing 49 forming part of a fluid delivery set 42 usable with a rotary peristaltic pump as shown in Figs. 5, 8 and 9. A first length of flexible tubing 39 of the fluid delivery set is connectable to or 5 integral with a supply container 91 and a third length of flexible tubing 64 of the fluid delivery set is connectable to or integral with a device for delivery of fluid into the body of a patient. A second length of flexible tubing 49 extends between the outlet of a drip chamber 43 and a 10 retention/connector element 56 that fit into respective supporting retentive receptacles or recesses, 44,55 in the pump housing 41. Intermediately, the length of flexible tubing 49 extends around the peristaltic rotor 52 of a peristaltic pump, the section 75, of the length of tubing 49 of which 15 assembly with a pinch valve element 80 forms a pinch valve, being on the downstream side of the peristaltic rotor 52 when the fluid delivery set 42 is mounted on the pump housing 41. Preferably, the first and third lengths of tubing 39, 64 are made of polyvinyl chloride (PVC) and the second length of tubing 49 is made of an elastically flexible silicone rubber.

The flexible tubing 49 of the fluid delivery set 42 is not under tension prior to mounting on a pump housing such that, as depicted in Fig. 6, the shank portion 84 of the pinch 20 valve element 80 pulls the respective tubular segment end portions 82,83 close enough together that the section 75 of

27

the flexible tubing 49 encompassed between the tubular segment end portions is doubled over and pinched or kinked to the point of occlusion of the lumen defined by the tubing wall. The length of flexible tubing 49 of the fluid delivery set 42 is depicted in Fig. 7 as it would appear when the fluid delivery set is mounted on a pump housing and the length of flexible tubing which extends between the drip chamber 43 and the retention/connector element 56 and intermediately is stretched around the peristaltic rotor 52 of the peristaltic pump. Consequently, the tension on the flexible tubing 49 stretches the shank 84 of the pinch valve element enough to straighten out the pinched section 75 of the flexible tubing 49 sufficiently that the pinch valve is opened for fluid to move therethrough. Put another way, the lumen in the flexible tubing is opened or closed in response to the amount of tension on the tubing.

The pinch valve of the invention is useful also as a part of fluid delivery sets fitting on rotary peristaltic pumps with housings of various configurations, such as the prior art pump depicted in Fig. 10. The pinch valve in the fluid delivery set 42p mounted on pump housing 41p as seen in Fig. 10 is under sufficient tension to stretch the shank portion 84p of the pinch valve element so that the pinch valve is open to fluid flow. The pinch valve of the invention is also useful in many other settings in which fluid is to be

28

delivered through a flexible tubing, including in-line peristaltic pumps, where there is a need for automatic means for halting fluid flow in the event an essential configuration of the flexible tubing should become somehow altered.

In Fig. 12 there is shown an alternative pinch valve element 80a having a substantially rectangular substantially planar shank portion 84a connecting substantially rectangular substantially planar end portions 82a, 83a. The end portions 82a, 83a each have a concave surface adapted to fit conformingly against the outer cylindrical surface of the flexible tubing 49 and are bonded or cemented thereto, as seen in Fig. 11, after bending the flexible tubing section 75 so that attachment can be made with the length of the shank portion 84a much shorter than the length of encompassed flexible tubing section 75 in the resulting pinch valve.

In Fig. 14 there is seen another alternative pinch valve element 80b that is shaped like the capital letter "I" and formed of a flat, sheet-like, elastic, flexible, polymeric material. The pinch valve element 80b is attached to the flexible tubing 49 by wrapping the wider sheet-like end portions 82b, 83b substantially around the flexible tubing and bonding or cementing them thereto as seen in Fig. 13 at locations spaced further apart longitudinally of the flexible tubing 49 than the length of the shank portion 84b whereby the flexible tubing section 75 between the end portions 82b, 83b is

29

doubled over and pinched shut as shown in Fig. 13 when the flexible tubing 49 is not under longitudinal tension.

Yet another alternative pinch valve element 80c is seen in Fig. 16 in which a shank portion 84c having an arcuate cross section of half-cylinder or hemi-cylindrical shape joins arcuate end portions 82c, 83c that are arcuately slotted on the concave surface that is mated with the cylindrical outer surface of the flexible tubing 49 as shown in Fig. 16a. As in the case of the other pinch valve embodiments depicted herein, the flexible tubing 49 is bent during the assembly of the pinch valve seen in Fig. 15 so that the encompassed section 75 of the flexible tubing will be much longer than the shank portion 84c of the pinch valve element. Thermal bonding or cementing of the pinch valve element end portions 82c, 83c to the flexible tubing 49 completes the manufacture of the pinch valve shown in Fig. 15.

Still another alternative pinch valve element 80d is shown in Fig. 18 in which a shank portion 84d and end portions 82d, 83d are all part of one hemi-cylindrical sleeve-shaped piece of elastically flexible polymeric material which is shown in Fig. 17 attached, for example by bonding or an adhesive, to flexible tubing 49 to form another embodiment of the pinch valve of the invention. Again, in bonding or cementing the shank portion 84d to the flexible tubing 49, the tubing section 75 is bent sharply so that the end portions

30

82d, 83d of the pinch valve element will be attached at locations longitudinally spaced along the flexible tubing 49 such that tubing section 75 will be substantially longer than shank portion 84d to provide the tension responsive valve effect.

Another embodiment of a pinch valve element 80e is depicted partly, and also entirely, assembled with a length of flexible tubing in Figs. 19-21. Pinch valve element 80e comprises foreshortened tubular segment end portions 82e, 83e joined by a strip or rod-like shank portion 84e. The end portion 82e is initially insert molded to the flexible tubing 49, as is positioning collar 60 which is spaced apart from the end portion 82e by the intended length of encompassed flexible tubing section 75. The section 75 of the flexible tubing 49 between the tubular segment end portion 82e and positioning collar 60 is then bent sharply and tubular segment end portion 83e is slipped over the adjacent end of flexible tubing 49 until the end portion 83e is against the positioning collar 60 where the tubular segment end portion 83e is bonded or cemented in place, thus forming the pinch valve depicted in Fig. 20. As shown in Fig. 21, when the tubing 49 is placed under sufficient longitudinal tension, shank portion 84e yields and encompassed flexible tubing section 75 straightens out sufficiently that fluid may flow therethrough.

Referring now to Figs. 22-24, another embodiment of a

31

pinch valve element 80f is seen having closed loop or eye-like end portions 82f, 83f joined by a narrower shank portion 84f. An end portion 82f of the pinch valve element is emplaced telescopically around the flexible tubing 49 a selected distance from an end thereof and the flexible tubing is then bent sharply between the position of the end portion of the pinch valve element 82f and the nearest end of the flexible tubing and the other end portion 83f is telescopically emplaced around the flexible tubing to a position defining flexible tubing section 75 and the end portions are bonded or cemented in place. For example a room temperature vulcanizing silicone polymer composition may serve as a suitable adhesive to be inserted along or just under the margins of the pinch valve element end portions. The completed pinch valve is tension responsive, kinking shut when not under tension as seen in Fig. 23 and being openable under sufficient tension as depicted in Fig. 24.

Referring now to Fig. 25, still another form of tension responsive pinch valve is made by molding a sharply bent piece of a highly elastic springy material, such as metallic spring wire 181, or a suitable springy polymeric material, in the wall 182 of a length of flexible tubing. The memory of the sharply bent springy material causes the flexible tubing to be pinched shut when there is not enough longitudinal tension applied to the flexible tubing. As seen in section in Fig. 26,

WO 97/11296

32

the wall 182 of the tubing is made thicker along a longitudinal side to accommodate the molding or extruding of the high elastic springy material 181 therewith. Alternatively, a sharply bent piece of a highly elastic springy material, such as a spring wire 181, or a suitable polymeric material, may also be molded onto the outside of the wall 183 of the flexible tubing as indicated in section view in Fig. 26A.

Utilizing another mode of action a tension responsive pinch valve is made using a springy pinch valve element that is pre-formed with a memory that causes the ends of the valve element to twist sufficiently to close the lumen of a flexible tubing telescopically embraced by the valve element. Such a pinch valve element is identified by the reference numeral 80g in Fig. 27 where the pinch valve element, having tubular segment end portions 82g, 83g and a shank, in the form of a plurality of longitudinal ribs 84g that are helically twisted, connecting the end portions, is shown assembled telescopically on a length of a length of flexible tubing. During assembly, the pinch valve element 80g is placed under longitudinal tension to straighten the longitudinal ribs 84g while the length of flexible tubing 49 is inserted through the pinch valve element and bonded or adhesively attached while the longitudinal tension on the pinch valve element 80g is maintained. On relaxing the longitudinal tension on the

33

assembled pinch valve, the pinch valve element 80g twists the encompassed section of the flexible tubing, pinching it shut. Under tension, the resulting pinch valve untwists to unpinch the flexible tubing, permitting fluid passage therethrough.

It is thus evident that many embodiments of the pinch valve element employed in the tension responsive pinch valve of the invention may be made in many different forms from elastically flexible polymeric material and shaped to have two end portions connected by a shank portion. The end portions must be attachable to the flexible tubing of which the pinch valve is formed and must be attached with the end portions spaced apart a greater linear distance along the flexible tubing than the length of the unstretched shank portion of the pinch valve element, a relative distance in the range of about 4:1, varying only slightly as will at once be apparent, according to the elastic yield strength of the shank portion of the pinch valve element and the bend strength modulus of the flexible tubing, so that the encompassed tubing section will be pinched or kinked sharply enough by the pull of the shank portion when the pinch valve is not under tension that shut-off or occlusion of fluid flow through the flexible tubing will take place.

In all embodiments the shank portion must deform elastically under appropriate tension for the setting in which the valve is used that the pinch valve will open under

34

longitudinal tension applied to the flexible tubing for the operations or procedures being carried out, yet close when the tension is released or absent.

A tension responsive pinch valve of the type shown in Figs. 1-10 has been assembled by emplacing the pinch valve element upon a length of tubing using the assembly apparatus disclosed herein which has utility for placing a flexible, and at least somewhat elastic, foreshortened tubular segment telescopically upon and near an end of a length of tubing having an outer diameter substantially the same or greater than the inner diameter of the tubular segment. A very important aspect of the assembly apparatus disclosed herein is the capacity to eject the assembled combination of a flexible tubular segment and a length of tubing from the assembly apparatus without displacing the flexible tubular segment longitudinally along the length of tubing.

For the purposes of the specification and claims it should be understood that the front side or surface, also referred to herein as a first surface, of the assembly apparatus is the side or surface into which the length of tubing is inserted for emplacement of a flexible tubular segment thereon, while the back or rear side or surface is opposite the front side or surface. A forward motion is a motion towards the front side or surface as here defined, while a rearward motion or extension is taken in the opposite

direction.

As seen in the exemplary embodiment shown in Figs. 28-30, and the view in section in Fig. 32, along with the exploded view in Fig. 33, the present assembly apparatus is made up of 5 a body portion, indicated generally by the reference numeral 341; which may if desired have a base support portion 342, which may be secured to a base plate 343, for example by bolts 403, if desired, for stability during use. It is to be understood that the support structure may take any suitable 10 shape and orientation and the parts thereof attached together by any suitable means such as welding or clamping.

As seen in Fig. 33, the exemplary assembly apparatus 15 consists mainly of the body portion and suitable base or support portions, in addition to a sub-assembly, indicated generally by the reference numeral 330, a cover plate 347, a first retainer ring 352, a control ring 357, a second retainer ring 366 and a rear support element 374. In the assembled 20 apparatus the sub-assembly 330 having controllably spreadable and retractable spreader finger portions is positioned in a cylindrical bore 344 that extends through the body portion 341 from the first, or front, face to the second, or rear, face and the other components are attached in the sequence and 25 positions indicated, using screws and bolts 402, 405, 406, 407, 408 or other suitable fastening means.

The combination of the sub-assembly 330 with spreader

finger elements 339, as seen in exploded view in Fig. 37, together with the cover plate 347 and the control ring 357, when mounted in the body portion 341 comprises a mechanical means for assembling a tubular segment with a length of 5 tubing. Moreover an integral part of the sub-assembly positioned concentrically and reciprocably within the mechanical means for assembly constitutes means for ejecting an assembly of a tubular segment with a length of tubing as will be further described herein.

The means for assembly which includes mechanical means for spreading and retracting the spreader finger element 339 is described in detail below and is comprised primarily of: 10 (1) a substantially cylindrical rotatable sleeve 149, that is rotatable in the cylindrical bore 344 of the body portion 341 of the apparatus; (2) a control ring 357 for rotating the rotatable sleeve 149; (3) a disc-like member 354 having radially, i.e., spirally, extending spiral guideways 360 formed therethrough and being mounted co-axially upon a first 15 end of the rotatable sleeve 149 in an annular recess; and (4) at least three spreader finger elements, indicated generally by the numeral 339, that are supported by a combination of the disc-like member 354 and the cover plate 347 and radially 20 spread or retracted by co-action of the disc-like member and the cover plate with the spreader finger elements.

The ejector means comprise: (1) a reciprocable piston

362, depicted in Figs. 36 and 37 as part of the assembly apparatus shown in differing stages of the assembly process; (2) an ejector block 368 or 368a as depicted in Figs. 34 and 35; and (3) ejector arms 371, in addition to the rotatable 5 sleeve 149 in the cylindrical passageway of which the piston 362 is reciprocable.

The subassembly identified by reference character 330 in Figs. 33, 37, 39 and 40, includes the substantially cylindrical rotatable sleeve 149 with a cylindrical passageway 10 extending therethrough and into which there is positioned co-axially the reciprocable piston, indicated generally by the numeral 362. The reciprocable piston has a recess in one end into which there is positioned co-axially an ejector block such as ejector block 368 or 368a depicted in Figs. 34 and 35. 15 The ejector block has a plurality, in this example three, longitudinal slots 370 therein and in which are pivotally mounted, using pins 371b, ejector arms 371 substantially parallel to the longitudinal axis of the piston 362, bearing in mind that when the assembly apparatus is fully assembled, 20 the piston is co-axial with the bore 344 through the body portion 341.

In a recess in the first end 365 of the piston 362 there is mounted in any suitable manner an ejector block 368, such as the ejector block shown in Fig. 34. The ejector block 25 shown in Fig. 34 has a rearwardly extending tongue-like

portion 338 that fits into a complementary borehole or passageway 336 in the piston 362 and is secured by a setscrew 337. The overall longitudinal length of the ejector block used in the assembly apparatus determines the distance from 5 the end of the length of tubing where the tubular segment will be emplaced during the assembly process.

In assembling a pinch valve element with two tubular segments as end portions it is necessary to assemble each tubular end portion with a given length of tubing in a 10 separate operation in which an assembly apparatus is used with an ejector block having the appropriate length. Thus a shorter ejector block such as that shown in Fig. 34 would be used to emplace the first tubular segment, e.g. 82, while a longer ejector block 368a, as shown in Fig. 35, would be used 15 in assembling the second tubular segment, e.g. 83, with the length of tubing to get the proper positioning of the tubular segments and achieving also the proper spacing longitudinally along the flexible tubing between the tubular segments. The ejector block 368a is provided with a forwardly projecting axial extension 338b that has a large enough cross-section to 20 serve as a stop for the length of tubing, but is small enough to facilitate use of a coil spring 363 to make the piston 362 recoil after the ejection step.

In assembling the present apparatus the subassembly 330 25 seen in Fig. 33 is made up by selecting an ejector block 368

39

(or alternatively ejector block 368a of Fig. 35) of suitable dimensions, such as the ejector block depicted in Fig. 34, and positioning a plurality of pivotal ejector arms 371 in respective slots 370 formed in the sides of the ejector block 368 where the ejector arms are pivotally retained by pins 371b that pass through the walls of the slots and through the ejector arms near a first end 333 of each arm. The number of ejector arms 371 and complementary slots 370 employed is preferably at least three to match the number of spreader finger elements 339. The ejector arms 371 are oriented substantially parallel to the axis of the ejector piston 362. The rearward projecting tongue-like portion 338 of the ejector block 368 is inserted into the axial borehole 336 in the end 365 of the piston 362 and secured with a set screw as shown in Fig. 32.

Referring now to Figs. 32 and 37, an elongated central guide rod 369 is inserted into and secured in any suitable manner in a longitudinal axial borehole 334 in the free end of the ejector block 368, or, in a longitudinal axial borehole 334a of the axial extension 338b of ejector block 368a if the longer extension block is part of the subassembly.

Turning again to Figs. 36 and 37, an elastic annular member 372, which may be a conventional "O"-ring, is placed around the ejector arms 371 at about mid-length, for example at notches 335 in the arms, to retain them clustered together

40

around the spreader finger portions 358 in the final assembly. Adjacent the second end 332 of each of the ejector arms 371 is an elongated longitudinally extending slot 373 formed therethrough. Through each of the slots 373 a respective leg portion 356 of a spreader finger element 339 extends radially outward from the line of the axis of the piston 362. As seen in Figs. 37, 38 and 40, the spreader finger elements 339 are "L"-shaped, each with a leg portion 356 and a thin finger, i.e., finger portion, 358. To accommodate reciprocal movement of the ejector arms 371 along the axial line during an ejection step without interfering with the normal function of the spreader finger elements 339, the leg portion 356a that joins the finger portion 358 to the leg portion 356 in each element is preferably made thin enough so that the sides of the slot 373 do not bind against the leg portion 356a.

The means for assembling a tubular segment telescopically upon a length of tubing form part of the subassembly 330, which includes the spreader finger elements 339. The mechanical means for radially spreading the spreader finger portions include the disc-like member 354 as well as the rotatable sleeve 149 on which the disc-like member 354 is mounted. The cover plate 347 with its radial channels 355, while not part of the subassembly 330, is also an essential part of the mechanical means for spreading and retracting the spreader finger portions in cooperation with the disc-like

41

member 354 and its spiral guideways 360.

As best seen in Fig. 38, each spreader finger element 339 is provided with a guide pin 359 that extends laterally from about mid-length of the leg portion 356 so as to extend into a spiral guideway 360 of the immediately adjacent disc-like member 354. With the spreader finger elements 339 restricted by the radial channels 355 of the cover plate 347 so that they cannot rotate, rotation of the disc-like member 354 provides cam-like action as the guide pins 359 are forced to slide along the respective spiral guideways 360, moving the spreader finger elements 339, and their finger portions 358, radially outward or inward, depending on the direction of rotation.

In further assembling the subassembly 330 of Fig. 33, as seen in Fig. 39, a coil spring 363 is slid over the cluster of ejector arms 371, followed by the disc-like member 354 preparatory to attaching it as by threaded fasteners 401 to the annular end face of the rotatable sleeve 149, after sliding the piston 362 further into the passageway of the rotatable sleeve 149, as seen in Fig. 40. Also seen in Fig. 40 are the spreader finger elements 339 positioned with the finger portions 358 clustered concentrically inside the cluster of ejector arms 371 and around the central guide rod 369.

The subassembly 330 seen in Fig. 33 and largely contained within the rotatable sleeve 149 can now be inserted into the

42

body portion 341 from the first or front side 345 thereof into the bore 344 and partially extending beyond the second or rear side 346 of the body portion 341 and positioned as seen in Fig. 32, so that the cover plate 347 can be attached by threaded fasteners 402, preferably using a locating pin 404 to align the grooves in the back side of the cover plate (described below) in the required operative orientation. The inside face, i.e. the back side, of the cover plate 347, as seen in Fig. 41, is formed with radial channels 355 in which the respective leg portions 356 of the spreader finger elements 339 are reciprocable when positioned therein with the cover plate attached with the inside face turned face to face with the disc-like member 354. The radial channels 355 formed in the inside face of the cover plate 347 and with the leg portions of spreader finger elements 339 are, of necessity, open toward the disc-like member 354 so that the guide pins 359 can extend into, and slide along, the spiral guideways 360.

Referring again more particularly to Figs. 32 and 33, the body portion 341 is seen to encompass the cylindrical bore 344, which is of relatively large diameter compared to the body portion, and extends from the first surface or side 345 to the second surface or side 346 of the body portion. While the assembly apparatus is shown in the drawing figures supported upon a base with the assembly apparatus oriented to

43

receive an end portion of the length of tubing disposed substantially horizontally during the assembly procedure, it is to be understood that the base may be modified, if desired, to support the apparatus with the bore tilted upwardly at any angle to receive the length of tubing, including facing substantially vertically upward, without departing from the scope of the invention. In such event the first or front side of the apparatus as here described would be the upper or top side or surface and the second or back or rear side would be the lower or bottom side or surface of the assembly apparatus.

The first surface 345 of the body portion 341 is substantially covered by the circular cover plate 347 with an aperture 347a located at the center thereof, while the second surface 346 of the body portion 341 is faced with a first retainer ring 352 that has a slightly smaller inner diameter than the diameter of the cylindrical bore 344. The cover plate 347 and the first retainer ring 352 are fastened to the body portion 341, for example, by screws 402, 405, respectively but it is to be understood that any suitable means of retaining these components in their relative operable positions may be employed.

As best shown in Figs. 32 and 33, within the cylindrical bore 344, as indicated above, is a rotatable substantially cylindrical sleeve or tube 149, having a first end 350 and a second, smaller, end 351. The rotatable sleeve 149 is

44

retained in the cylindrical bore 344 by a flange or shoulder 353 of the rotatable sleeve which mates with, or fits against, the radially inner portion of the first retainer ring 352 in the vicinity of the second surface 346 of the body portion 341 and a radially outer, forwardly projecting, flange portion 350a of the first end of the rotatable sleeve is retained by the cover plate 347. While the first end portion 350 of the rotatable sleeve 149 has a larger outer diameter than the second end portion 351, hence the flange or shoulder 353, the inside diameter of the cylindrical passageway through the rotatable sleeve is uniform, and the rotatable sleeve will be referred to herein as substantially cylindrical. The second end 351 of the rotatable sleeve 149 is disposed outside of the cylindrical bore 344 and the first retainer ring 352 and is concentrically surrounded by a rotatable control ring 357, preferably of slightly greater diameter than the first retainer ring 352 and preferably having a knurled perimeter surface and/or a lever 361 extending therefrom for easy manipulation. The control ring 357 is bolted or otherwise attached in any suitable manner to the rotatable sleeve 149.

The first end 350 of the rotatable sleeve 149 has a recessed annular end face, having a perimeter flange 350a, as indicated. In the annular recess radially inward from the flange 350a is fitted the disc-like member 354 that is bolted or otherwise fixedly attached to the end face and has a

45

central aperture 354a the same diameter as the central aperture 347a of the cover plate 347, but slightly smaller than the inner diameter of the passageway through the rotatable sleeve 149. The rotatable disc-like member 354 has one face contacting the face of the annular recessed end of the rotatable sleeve 149 to which it is attached and the opposing face is face to face with and rotatable against the inside face of the front cover plate 347, which is attached to the body portion 341 and not rotatable.

As seen in Figs. 48 and 50 in dotted outline and in perspective in Fig. 41, the reverse side of the cover plate 347 is provided with three equiangularly-spaced channels 355 which are open sided towards the disc-like member 354 and extend radially outwardly from the central aperture 347a of the cover plate. Inserted reciprocably in each radially extending channel 355 from the central aperture 347a is a leg portion 356 of an "L"-shaped spreader finger element indicated generally by the reference numeral 339. The spreader finger portions 358 extend out of the central aperture 347a of the front cover plate 347 substantially parallel to the axis of the bore 344 to form a cluster and it is this cluster that is manipulated radially apart to spread a tubular segment, such as a tubular segment end portion of a pinch valve element, to permit telescopic assembly thereof upon, i.e., concentrically with, a length of tubing. The spreader finger portions 358,

46

upon which tubular segments are placed for spreading, i.e., stretching to a larger cross-sectional opening, during telescopic assembly of a flexible tubular segment with a length of tubing according to the invention, are preferably quite thin for easier removal of the assembled tubular segment and tubing combination from the assembly apparatus. In this regard it should be noted that the spreader finger portions 358 are sandwiched between a tubular segment end portion 382, 383 of the pinch valve element and the tubing 349 when the spreader finger portions are retracted prior to the ejection step.

In Figs. 37, 39 and 40, the disc-like member 354 is shown to have formed therein three parallel and radially, i.e. spirally, outward extending spiral guideways 360 which are open-sided towards the cover plate 347. Each spiral guideway extends spirally out in the same direction of rotation from the central aperture 354a of the disc-like member 354. Each leg portion 356 of a respective "L"-shaped spreader finger element 339 is provided with a guide pin 359 fixedly attached thereto that extends laterally from the radial channel 355 of the cover plate 347, in which the leg portion 356 reciprocates, into one of the spiral guideways 360 along which it is slidably. Instead of the spiral guideways shown cut entirely through the disc-like member 354, the guideways 360 may be grooves cut to the same pattern if they are each deep

47

enough to readily receive and slidably guide a guide pin 359 during rotation of the disc-like member 354 and the grooves are open sided towards the cover plate 347.

Upon rotation of the disc-like member 354, using the 5 knurled control ring 357 or the lever 361 to rotate the rotatable sleeve 149 to which the disc-like member 354 is attached, cam-like action is obtained to radially spread or retract the spreader finger portions 358 away from or towards the common axis as the leg portions 356 are moved radially by 10 the respective guide pins 359 sliding in the spiral grooves 360. If desired, the lever 361 may be attached to the control ring 357 as seen in Figs. 29 and Fig. 33 used to rotate the control ring 357 through a sufficient arc to obtain the desired spreading and retracting of the spreader finger 15 portions 358.

Positioned in the cylindrical passageway of the rotatable sleeve 149 and extending rearwardly therefrom is the reciprocable piston 362 that reciprocates through a short range of movement within the cylindrical passageway of the 20 rotatable sleeve 149 to carry out the very important ejection procedure. The piston 362 is urged resiliently out of the passageway of the rotatable sleeve 149 by the coil spring 363 that bears at one end of the coil spring against the annular portion of the face of the disc-like member 354 that extends 25 radially inward somewhat from the central aperture of the

48

rotatable sleeve 149, and at the other end, against the first end 365 of the piston 362. The rear portion 364 of the second end of the piston 362 is of a slightly smaller diameter than the first portion 365, the rear end of the larger diameter 5 portion constituting a shoulder on the piston, and a second retainer ring 366 attached to the control ring 357 has a central aperture smaller enough than the larger diameter of the first portion 365 of the piston to catch the shoulder and limit the reciprocation of the piston 362 in the rearward direction.

Mounted in a recess in the face of the first end 365 of the piston 362 is an ejector block 368 that is dimensioned longitudinally to serve as a stop to accurately limit the depth of insertion of a length of tubing on which a tubular segment, such as a pinch valve element, is to be emplaced.

In Figs. 53 and 54 there is shown an assembly apparatus with an ejector block 368a with a longer axial dimension that provides a shallower stop for tubing inserted into the apparatus for the purpose of assembling the second tubular segment end portion of a pinch valve element as a second step 20 in the process of assembling a pinch valve.

A central guide rod 369 extends axially from the ejector block 368 or 368a through the passageway of the rotatable sleeve 149 and substantially to the outward ends of the 25 spreader finger portions 358 where it is centered between

49

them. It serves as a guide over which the length of flexible tubing is inserted into the assembly apparatus. Also pivotably mounted are ejector arms 371 that extend forwardly along inside the passageway of the rotatable sleeve 149 and nearly 5 parallel to the common axis and out through the aperture 354a in the disc-like member 354 and aperture 347a in the cover plate 347 where they each rest against the radially outward surface of a spreader finger portion 358, being collectively resiliently urged against respective spreader fingers by a 10 springy resilient annular member 372, such as an "O" ring. The ejector arms 371 must be selected to be of the appropriate length to contact and bear against the edge of a flexible tubular segment, such as a tubular end portion of a pinch valve element, that has just been emplaced on a length of 15 flexible tubing extending into the apparatus, simultaneously with contact and pressure between the ejector block and the inner end of the flexible tubing within the apparatus, in order to avoid moving or displacing the tubular end portion longitudinally of the flexible tubing during ejection.

20 Because of the elastic radially inward tension of the tubular segment end portions of the pinch valve element upon the flexible tubing, which has an outer diameter as great or greater than the inner diameter of the tubular segments, it is not practically feasible to remove the assembled pinch valve 25 from the spreader fingers portion without risking altering of

50

the positions of the tubular segment end portions of the pinch valve element, unless use is made of the ejection components of the apparatus.

The second end or part 364 of the reciprocable ejection 5 piston 362 is shown in Figs. 29 and 32 to be supported by a support element 374 having a lower section 375 thereof attached to the rear of the base portion 342 of the assembly apparatus and an upright leg portion 376 extending upwardly to contact the rear part 364 of the piston which is slideable on 10 the flanged upper end 377 of the leg portion 376. A section 378 of the underside of the rear part 364 of the piston 362 is ground flat from adjacent the second end to the larger diameter forward part 365 of the piston 362, and it is this flat section that rests upon the flanged upper end 377 of the 15 leg portion 376 of the support element 374. The flat nature of the underside section 378 serves to prevent the piston 362 from rotating during use, and the shoulders 378a, 378b formed at each end of the flat section 378 catch, respectively, on the flanged upper end 377 of the support element 374 and on 20 the second retainer ring 366 to provide respective stop actions in the reciprocal motion of the piston 362.

In manufacturing a tension responsive pinch valve of the sort defined herein, it is essential to the proper valving action of the pinch valve that the tubular segment end 25 portions of the pinch valve element be positioned with some

51

accuracy spaced apart a rather short interval longitudinally, i.e., linearly, of the length of tubing, with the magnitude of the interval or spacing being substantially greater than the length of the shank of the pinch valve element. Such larger spacing linearly along the tubing is essential in order to obtain a doubling over of the tubing that produces a pinching shut of the embraced portion of the tubing when there is no tension on the portion of the length of tubing that includes the pinch valve ~~per se~~ and the shank of the pinch valve element tends to elastically assume about its normal length, drawing the attached tubular segment end portions mutually closer. Proper spacing during telescopic assembly is readily achievable in a convenient, efficient way using two nearly identical embodiments of the assembly apparatus described herein differing primarily in having ejector blocks of differing appropriate lengths to assemble the respective tubular segments. The ejector blocks serve as stops in indexing the length, or extent, the end of the length of tubing can extend into the assembly apparatus during the assembly process, thus controlling the positioning of the tubular segment end portions.

The first embodiment of the assembly apparatus utilized will have a relatively short ejector block, such as that identified by the reference numeral 368 in Figs. 32 and 36 and shown in perspective view in Fig. 34, so that the end of the

52

length of tubing will extend relatively deeper into the assembly apparatus and the first tubular segment end portion of the pinch valve element will be emplaced far enough from the inserted end of the flexible tubing to leave room for the necessary spacing between the first and the second tubular segment end portions. The telescopic assembly of the second tubular segment end portion can only be performed closer to the inserted end of the length of tubing, using the assembly apparatus, than the location of the emplacement of the first tubular segment end portion.

The second embodiment of the assembly apparatus used to telescopically assemble the second tubular segment end portion must have a longer ejector block such as that identified by the reference numeral 368a in Figs. 33 and 34 and shown in perspective view in Fig. 35, so that the flexible tubing will be stopped at a shallower depth for the assembly of the second pinch valve tubular segment end portion closer to the end of the length of flexible tubing than the first tubular segment end portion. The ejector block 368a may be seen in Fig. 35 to have a smaller diameter extension 338b that serves as the actual stop within the assembly apparatus for the end of the length of tubing inserted during assembly operations. The extension 338b has a smaller diameter than the ejector block 368a in order to leave circumferential annular space within the rotatable sleeve 149 for the coil spring 363.

53

The base, body portion, and parts such as the cylindrical sleeve, reciprocable piston, control ring and both retainer rings, cover plate and disc-like member, of the assembly apparatus may be made of mild steel or of an easily machinable metal, such as aluminum alloy, if desired, but are preferably made of tool steel or stainless steel. Preferably the spreader fingers and the ejector arms are made of tool steel or stainless steel to provide greater strength and durability in the thinner members.

Referring now to Fig. 42 there is depicted an embodiment of the assembly apparatus, along with a flexible pinch valve element 80 and a length 49 of flexible tubing of the same diameter depicted in exploded view. The pinch valve element 80, which consists of first 82 and second 83 foreshortened tubular segments as end portions joined by a short shank portion 84 of about the same length as the end portions, is about to be telescopically assembled on the length 49 of flexible tubing near an end thereof. The embodiment of the assembly apparatus shown in Fig. 42 is to be understood to be equipped with an ejector block 68 of appropriate length for positioning the first tubular segment 82 of the pinch valve element 80.

The pinch valve element 80 is seen in Fig. 43 to be poised for assembly on the length 49 of flexible tubing with the shank portion 84 of the pinch valve element bent aside to

54

hold the second tubular segment end portion 83 out of the way so the first tubular segment end portion 82 can be slipped over the spreader finger portions 358 that are retracted close together as a cluster as depicted in Fig. 43. In Fig. 44 the first tubular segment end portion 82 is shown slipped onto the cluster of spreader finger portions 358. The inner edge of the first tubular segment end portion should be in contact with the ends 337a of the ejector arms 331 to ensure accurate positioning during the assembly process. The section view in Fig. 45 also shows the tubular segment end portion 82 slipped onto the spreader finger portions 358. In Fig. 45 it is also seen that the apparatus is equipped with a fairly short ejector block 368 inside the first end of the ejector piston 362.

Rotation of the control ring 357, which concentrically surrounds and is attached to the rear end of the larger diameter portion of the rotatable sleeve 149, causes rotation of the rotatable sleeve as well as the disc-like member 354 which is mounted on the front end 350 of the rotatable sleeve. Rotation of the disc-like member 354 forces the guide pins 359 attached to respective leg portions 356 of spreader finger elements 339 to slide along the spiral guideways 360 of the disc-like member, giving cam-like action moving the leg portions 356 in a radial direction within the radial channels in the cover plate 347 and the spreader finger portions 358 of

55

the spreader finger elements 339 are consequently moved radially as well, which is the desired action. The direction and extent of rotation of the disc-like member 354 determines the radial direction and extent of movement of the spreader finger portions 358.

In the next assembly step the control ring 357 is then grasped and rotated manually, or the lever 361 may be used to rotate the control ring 357, in the appropriate direction and through an arc sufficient to spread the spreader finger portions 358, thus stretching the first tubular segment end portion 82 open as shown in Figs. 46, 47 and 48. Turning the control ring 357 sufficiently stretches the tubular segment 82 enough to admit the end of the length of tubing 49 which is then slid through the tubular segment with little or no friction and onto central guide rod 369 until the end of the length of tubing hits the ejector block 368, which serves as a stop for the proper positioning of the tubular segment end portion 82 on the length of tubing 49.

The control ring 357 is then rotated as by moving the lever 361 back towards its starting position to relax the spreading tension on the first tubular segment end portion 82, completing the assembly step for the first tubular segment end portion.

To carry out ejection, the ejector piston 362 is moved forward (towards the first surface 345 of the body portion

56

341) by any suitable means against the coil spring 363 to move the ejector piston a small distance or spacing from a position with the second or rear end 364 extending back beyond the support element 374 until the ejector piston 362 reaches a pre-set stop as seen in Fig. 49 where the rear edge 378a of the flattened lower surface 378 of the rear part 364 of the piston is caught by the upstanding flanged upper end 377 of the upright leg section 376 of support element 374. The piston 362 carries forward the ejector block 368 and the ejector arms 371 which contact and eject simultaneously and respectively the end of the length of tubing 49, and the nearest edge of the emplaced tubular segment 82 which is contacted by the ends of the ejector arms 371a, as can be seen in Figs. 49 and 50. At the pre-set stop the ejector arms 371 and the ejector block 368 will have coordinately mechanically ejected with simultaneous pressure the length 49 of flexible tubing and the emplaced first tubular end portion 82 of the pinch valve element.

While the piston 362 is readily slid forward manually towards the cover plate 347 if the coil spring 363 is selected to be of a suitable spring tension, the piston 362 may be equipped to be reciprocated hydraulically or electromagnetically, if desired.

In Fig. 51 the partly assembled pinch valve depicted in Fig. 49 is shown poised to be further assembled using a second

57

embodiment of the assembly apparatus with a different, i.e., shallower depth stop, in the form of a longer ejector block 368a with an extension 338b. The short end section 85 of the length 349 of flexible tubing between the leading end thereof and the emplaced first tubular segment end portion 82 of the pinch valve element 80 has been bent out of the way so as not to impede sliding the second tubular segment end portion 83 onto the retracted spreader finger portions 358 of the assembly apparatus until the tubular segment end portion contacts the ends of the ejector arms 71a, the shank portion 84 of the pinch valve element 80 being much shorter than the section of tubing 85a disposed between tubular segment end portions 82 and 83 which are assembled therewith (i.e. emplaced thereon).

The second tubular segment end portion 83 of the pinch valve element is then slid onto the spreader finger portions 358 and the control ring 357 is rotated to spread the spreader finger portions 358 and stretch the second tubular segment end portion 83 of the pinch valve element 80, similar to what is seen in Fig. 46, and the short end section 85 of the length 49 of flexible tubing is bent over sharply and the leading end is slipped inside the spreader finger portions 358 and the stretched second tubular segment end portion 83 and over the central guide rod 369 and up against the ejector block 368a as shown in Figs. 52 and 53.

58

As indicated, the longer ejector block 368a, having an extension 338b, provides a stop at a shallower depth of penetration by the end of the length of tubing 49 inside the apparatus. The ejector block 368a is selected to have an extension 338b of appropriate length to provide indexing at a selected depth of penetration desired for the end of the length of tubing 49 in order to achieve proper placement of the second tubular segment end portion 83.

To complete the assembly of the second tubular segment end portion 83 of the pinch valve element, the control ring 357 is rotated back to retract the spreader finger portions 358 closer together to relieve the tension on the second tubular segment end portion 83 as shown in Fig. 54. To carry out ejection substantially in the same manner as described for the first emplaced tubular segment end portion 82, the ejection piston 362 is pressed forward against the action of the coil spring 363 until the rear edge 378a of the flat lower surface 378 of the rear portion 364 of the ejection piston 362 is stopped by the flanged upper end 377 of the upright leg portion 376 of support element 374, whereupon the length 49 of flexible tubing and the second tubular segment end portion 83 of the pinch valve element emplaced thereon will be found to have been ejected as a unit and the manufacture of the flexible pinch valve is completed.

It is preferred to complete the manufacture of the pinch

59

valve by inserting a small amount of an adhesive such as a room temperature vulcanizing silicone adhesive along the margins of the tubular segment end portions of the valve element.

60

## CLAIMS:

1. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;  
the pinch valve element being fixedly associated longitudinally with the section of the length of flexible tubing and capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.
- 15 2. The tension responsive pinch valve of Claim 1 wherein the elastically flexible pinch valve element is assembled to the exterior surface of the section of the length of flexible tubing, the pinch valve element having first and second end portions and a shank portion connecting the end portions, the shank portion being longitudinally aligned with the section and the end portions being attached to the section at spaced apart points with the length of the section between the spaced apart points being sufficiently greater than the length of the

61

shank portion for the shank portion to pull the section into a sharp bend, pinching the lumen of the section shut, when the section is not under longitudinal tension.

3. The tension responsive pinch valve of Claim 2 wherein  
5 the length of the section of the length of flexible tubing  
between the spaced apart points is about 4 times as great as  
the length of the unstretched shank portion.

4. The tension responsive pinch valve of Claim 2 wherein  
10 the end portions of the elastically flexible pinch valve element are tubular segments that are telescopically assembled with the section of the length of flexible tubing and the outer diameter of the flexible tubing is at least as great as the inner diameter of the tubular segments.

15 5. The pinch valve of Claim 4 wherein the section of the length of flexible tubing is near an end of the length of flexible tubing.

6. The tension responsive pinch valve of Claim 2 wherein  
the end portions of the pinch valve element are non-tubular.

20 7. The tension responsive pinch valve of Claim 6 wherein  
the end portions of the pinch valve element are ring-like in

62  
shape.

8. The tension responsive pinch valve of Claim 1 wherein  
the pinch valve element is a sharply bent spring wire.

9. The tension responsive pinch valve of Claim 8 wherein  
5 the section of the length of flexible tubing to be reversibly closed has a tubing wall and the sharply bent spring wire is molded in the tubing wall.

10. The tension responsive pinch valve of Claim 8 wherein  
the section of the length of flexible tubing to be reversibly closed has a tubing wall and the sharply bent spring wire is molded longitudinally to the exterior of the tubing wall.

11. The tension responsive pinch valve of Claim 1 wherein  
the pinch valve element is capable of twisting the section of  
the length of flexible tubing to the point of pinching the  
15 lumen closed when the section is not under longitudinal tension.

12. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;

63

the pinch valve element comprising an elastic, flexible polymeric material and having a pair of tubular segment end portions joined by a shank portion, the tubular segment end portions being telescopically assembled with the flexible tubing and the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

13. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;  
the pinch valve element comprising an elastic, flexible polymeric material and having a rectangular substantially planar shank portion connecting rectangular substantially planar end portions each of which has a concave surface adapted to fit conformingly against an outer cylindrical surface of the flexible tubing and is bonded thereto, the pinch valve being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is

64

not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

5

14. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;

the pinch valve element comprising an elastic, flexible polymeric material and being formed in the shape of the capital letter "I" from a flat sheet, the end portions of the "I" being wrapped substantially around the flexible tubing and bonded thereto, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

20

15. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a

65

section to be reversibly closed as a valve;  
the pinch valve element comprising an elastic, flexible polymeric material and having arcuate end portions that are joined by a shank portion having an arcuate cross section, the end portions each having a concave surface that is mated with and bonded to the outer surface of the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

16. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;  
the pinch valve element being a hemi-cylindrical sleeve shaped piece of an elastic, flexible polymeric material, each end of the pinch valve element being attached to the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open

66

when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

5

17. A tension responsive pinch valve comprising:  
an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;

the pinch valve element comprising an elastic, flexible polymeric material with the pinch valve element having a pair of tubular segment end portions joined by a shank portion, one of the end portions being insert molded around the flexible tubing and the other end portion being telescopically emplaced around the flexible tubing and spaced apart from the first end portion by a positioning collar which is insert molded around the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

18. A tension responsive pinch valve comprising:

67

an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;

the pinch valve element comprising an elastic, flexible 5 polymeric material and having a pair of closed loop end portions joined by a shank portion, each end portion being telescopically emplaced around the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the 10 section of flexible tubing shut when the flexible tubing is not under tension, while allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

15 19. A tension responsive pinch valve comprising:

an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;

the pinch valve element being a sharply bent piece of a 20 highly elastic springy material molded into the wall of the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while allowing the

68

lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

5 20. A tension responsive pinch valve comprising:

an assembly of an elastically flexible pinch valve element and a length of flexible tubing having a lumen and a section to be reversibly closed as a valve;

the pinch valve element being a sharply bent piece of a 10 highly elastic springy material bonded to the exterior of the wall of the flexible tubing, the pinch valve element being capable of distorting the section of flexible tubing to the point of pinching the lumen of the section of flexible tubing shut when the flexible tubing is not under tension, while 15 allowing the lumen to open when the flexible tubing is under tension sufficient to elongate the pinch valve element and at least partially undo the distortion of the section of flexible tubing.

1/37

2/37

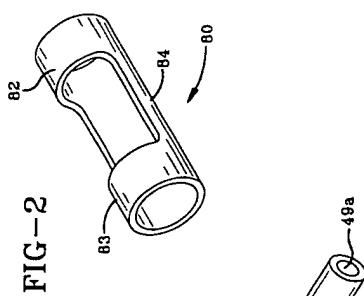


FIG-2

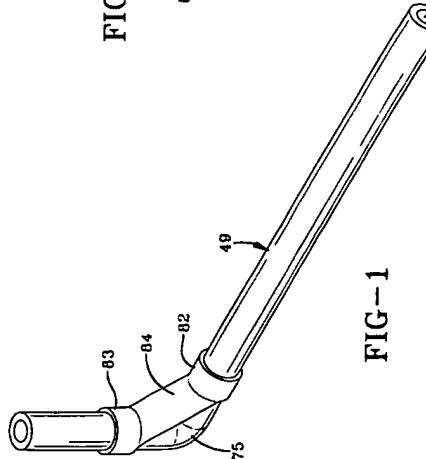


FIG-1

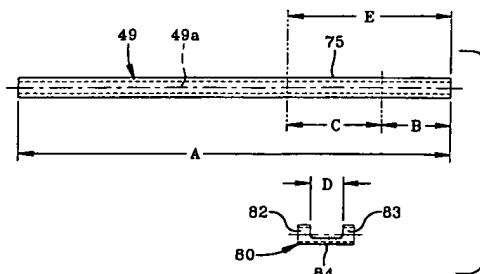


FIG-3

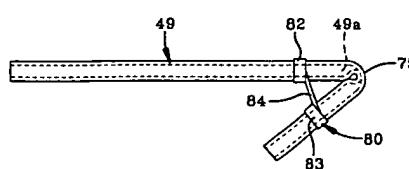


FIG-4

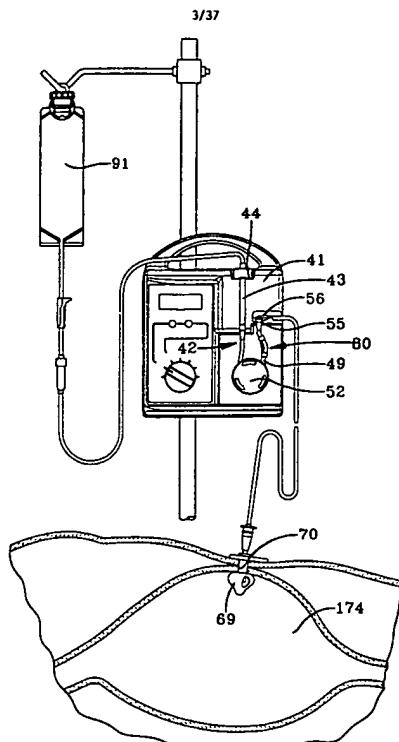


FIG-5

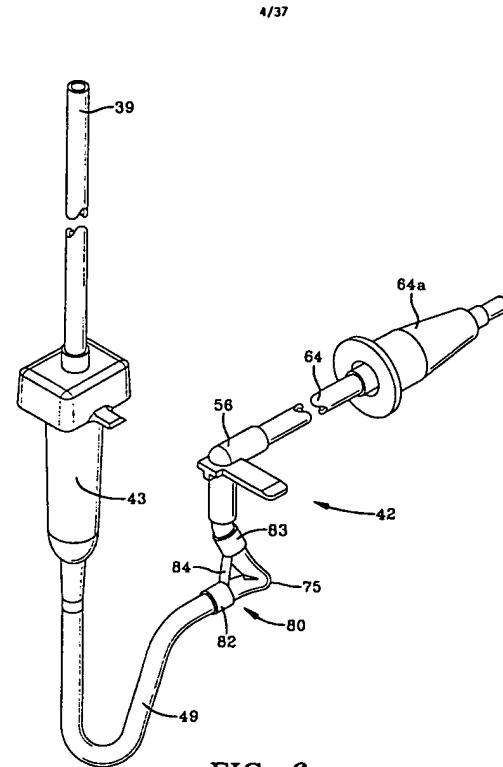


FIG-6

5/37

6/37

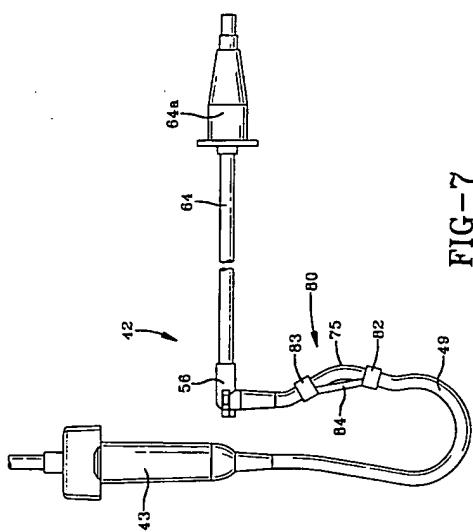


FIG-7

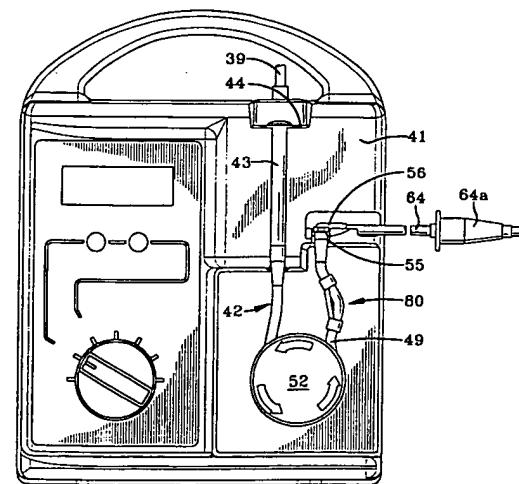
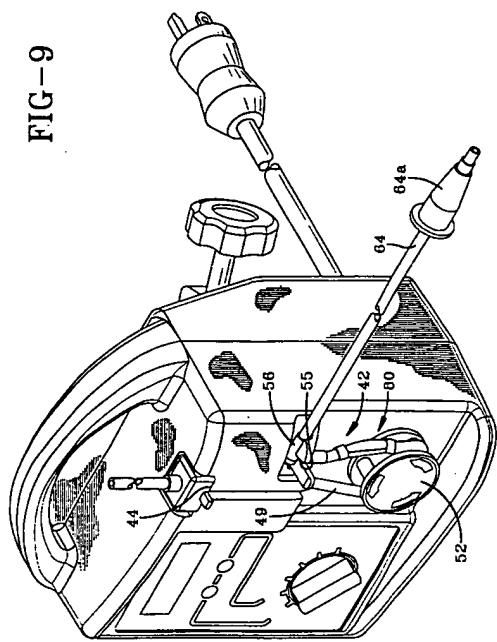


FIG-8

7/37

FIG-9



8/37

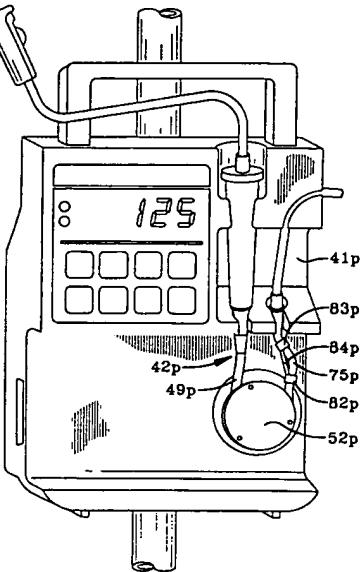


FIG-10

9/37

FIG-12

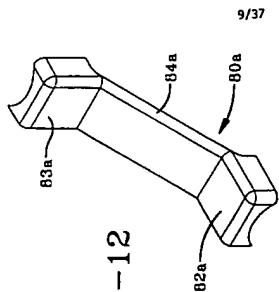


FIG-11

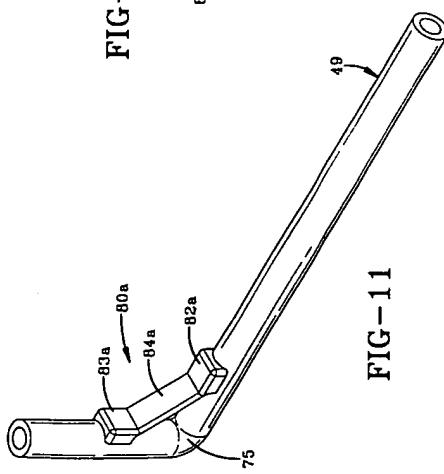


FIG-14

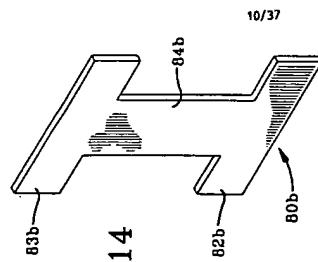
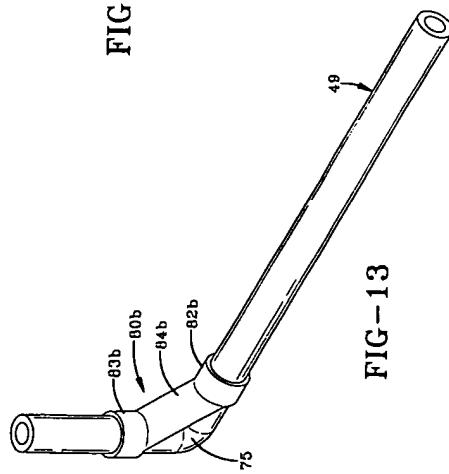
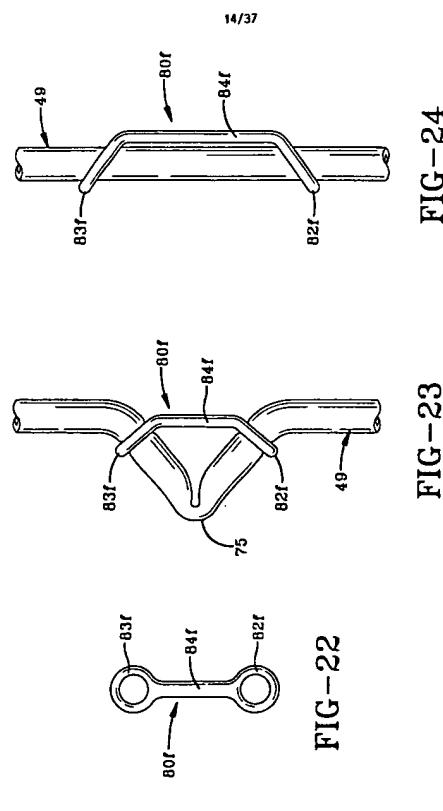
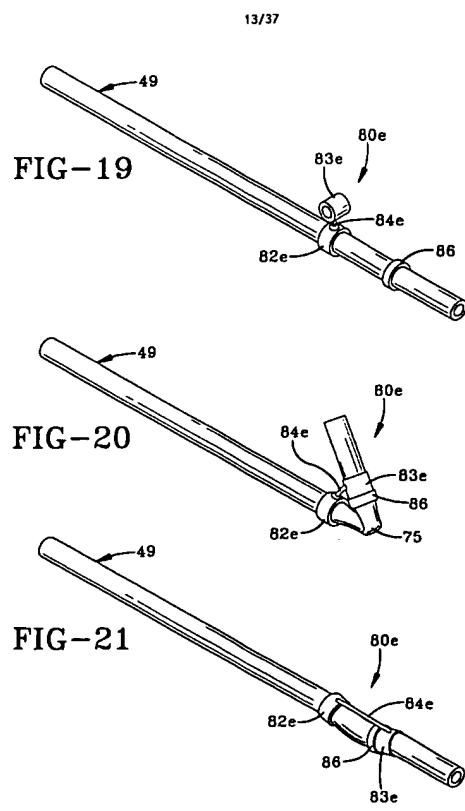
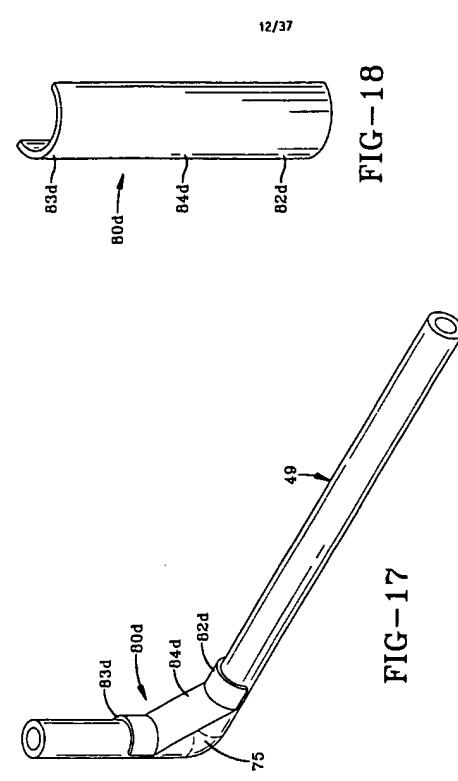
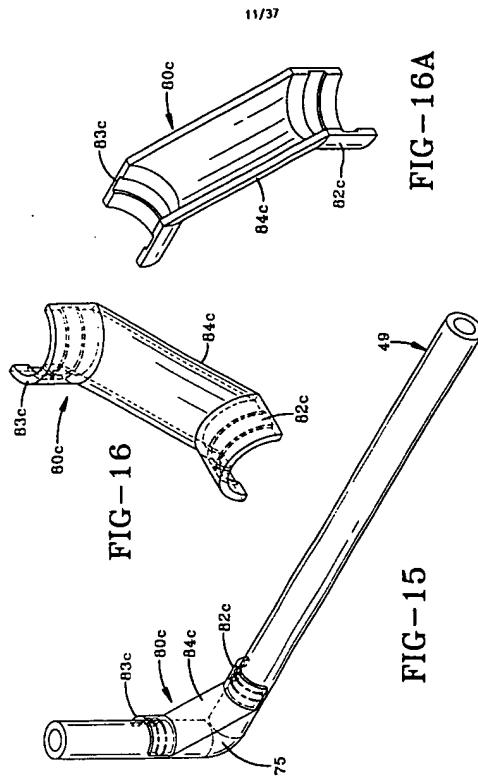


FIG-13





15/37

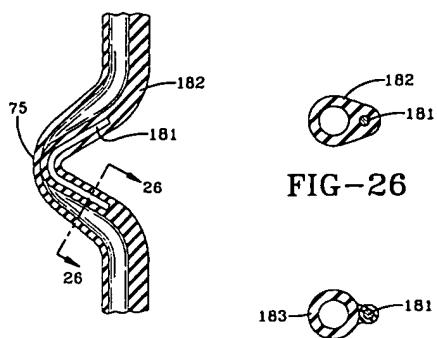


FIG-25

FIG-26

FIG-26A

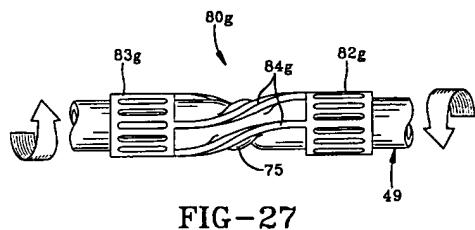


FIG-27

16/37

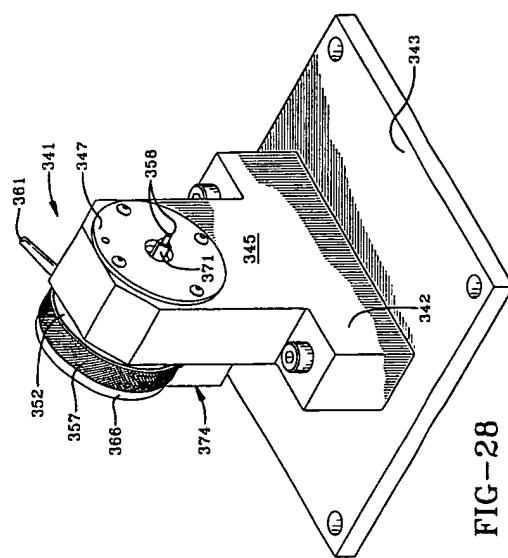


FIG-28

17/37

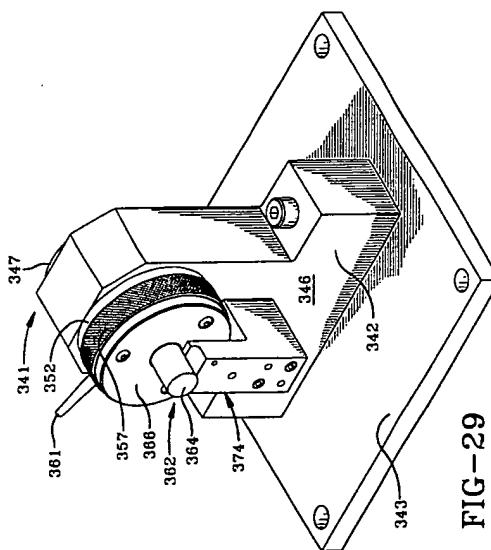


FIG-29

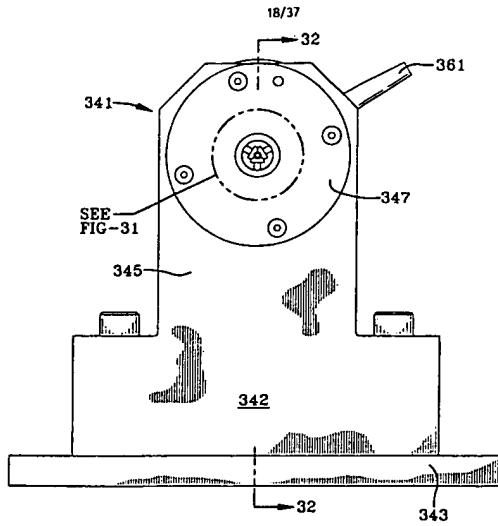


FIG-30

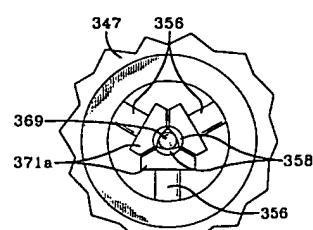


FIG-31

19/37

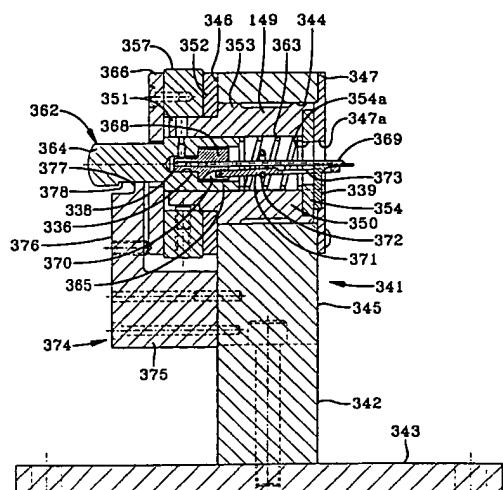


FIG-32

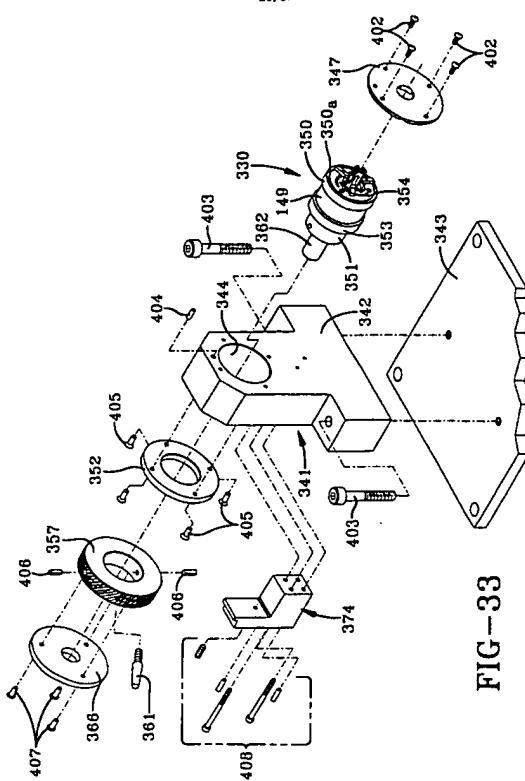


FIG-33

21/37

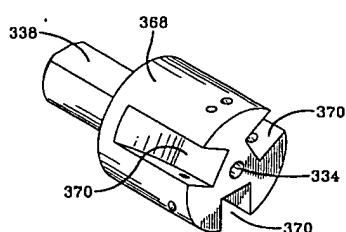


FIG-34

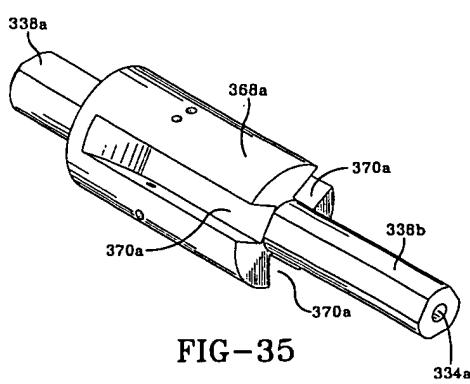


FIG-35

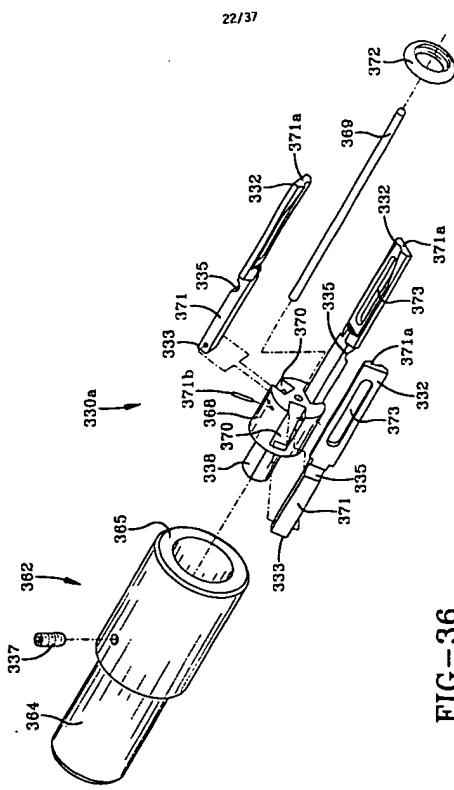


FIG-36

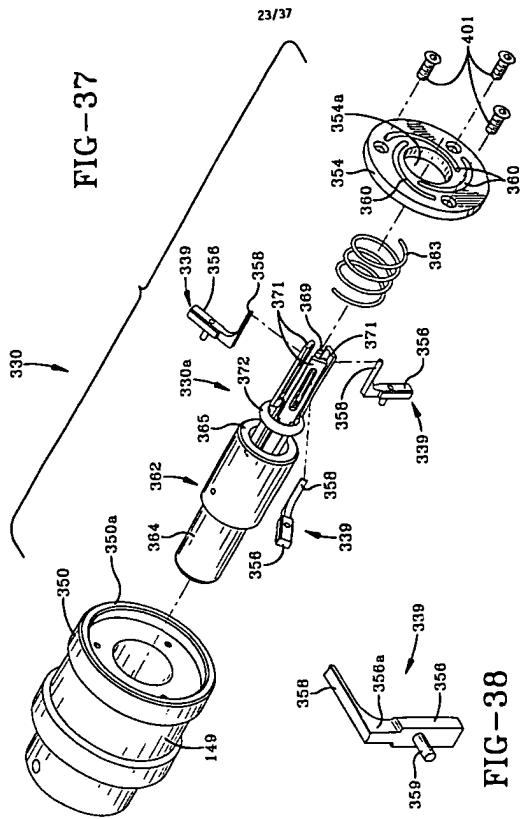


FIG-37

FIG-38

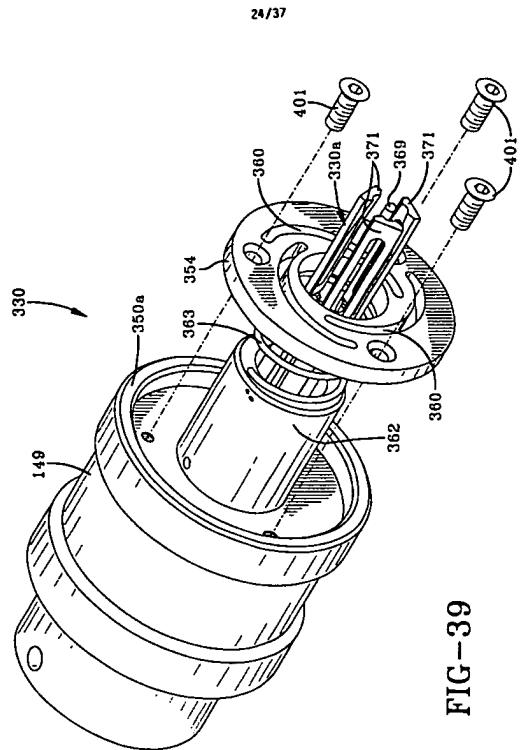


FIG-39

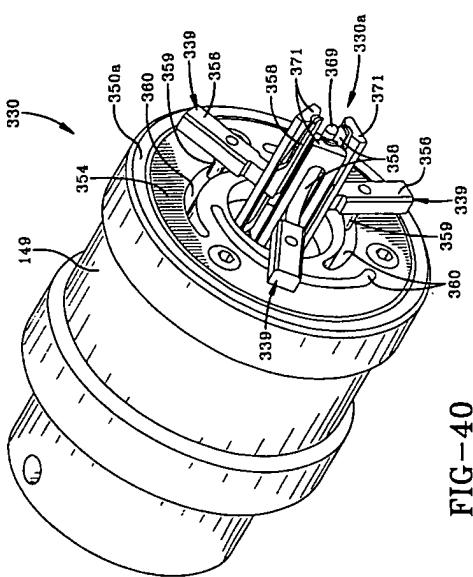


FIG-40

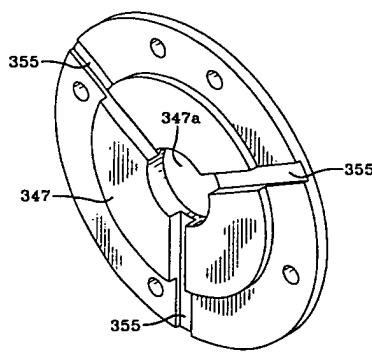


FIG-41

27/37

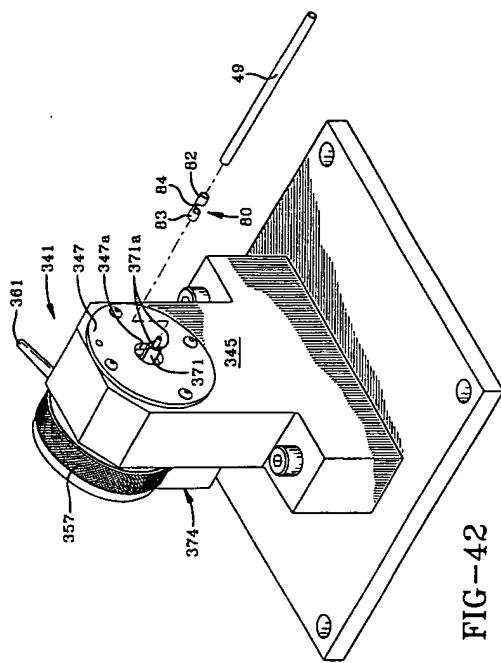


FIG-42

29/37

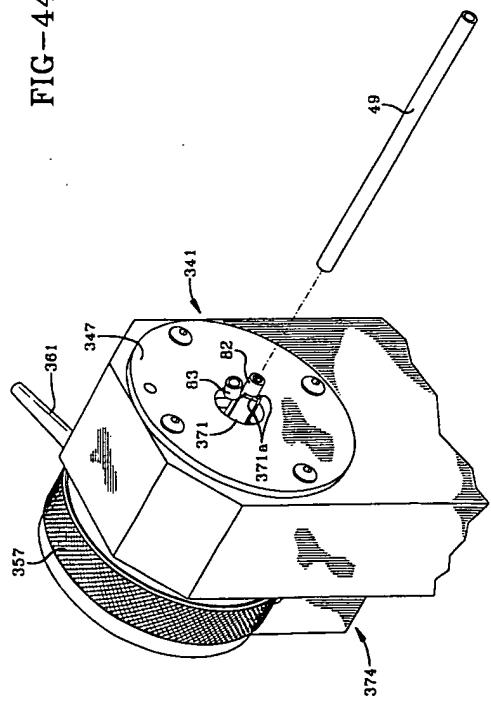


FIG-44

30/37

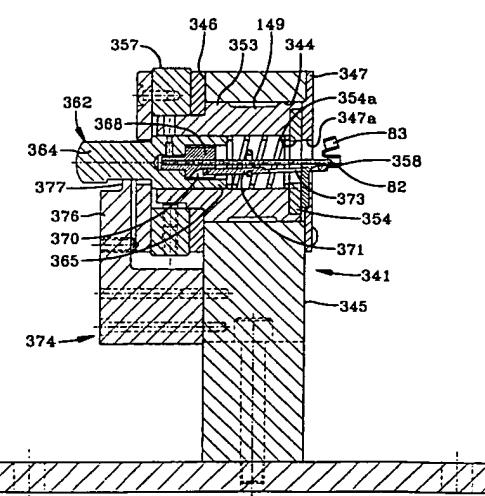


FIG-45

31/37

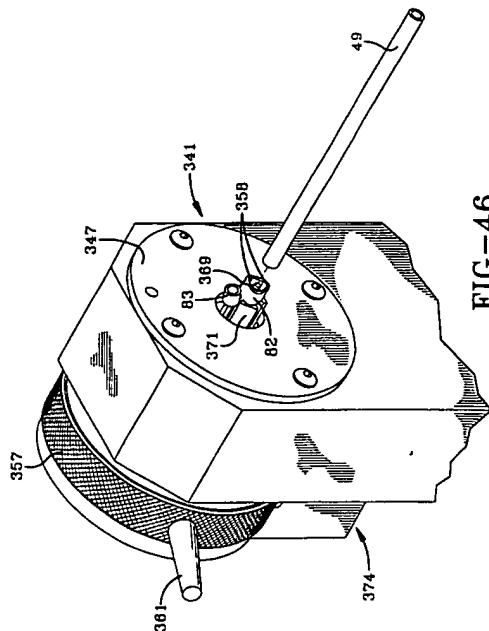


FIG-46

32/37

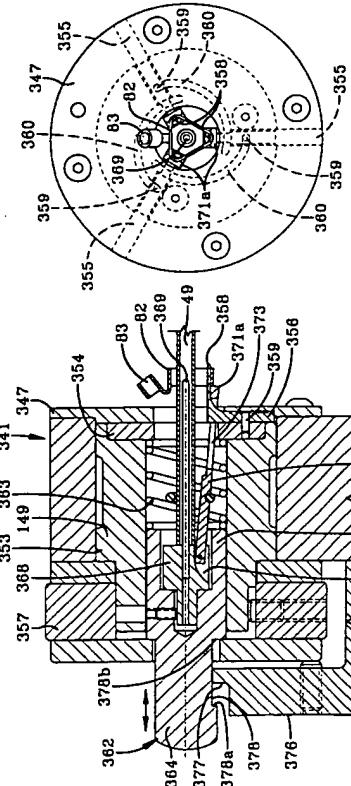


FIG-48

PCT

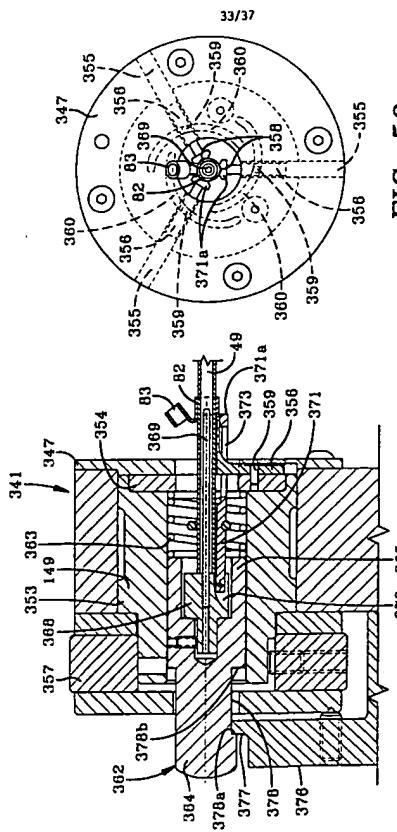


FIG-50

34/37

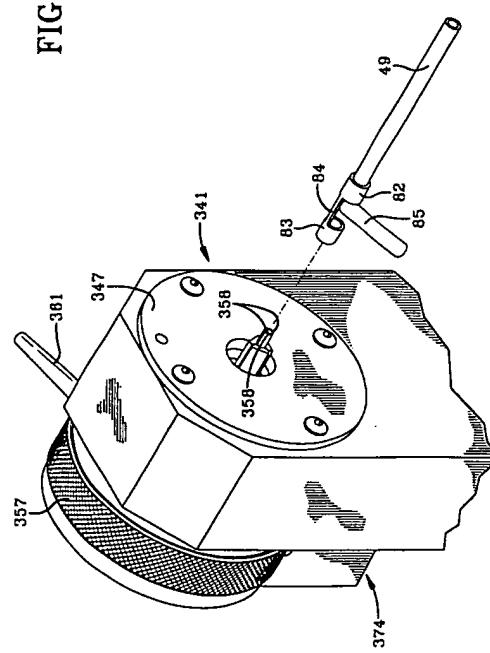


FIG-51



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 96/14602

## C (Continuation): DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 2716013 (T.B. TINKER), 23 August 1955 (23.08.55), column 2, line 3 - line 17, figures 1, 2 --	1,12
A	US, A, 2117071 (J.R. RING), 10 May 1938 (10.05.38), figures 1-4 --	8
A	US, A, 2844351 (R.C. SMITH), 22 July 1958 (22.07.58), column 1, line 55 - line 72, figure 1 --	11

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.  
PCT/US 96/14602

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 2444449	06/07/48	NONE	
US-A- 2002835	28/05/35	NONE	
US-A- 2922613	26/01/60	NONE	
US-A- 2716013	23/08/55	NONE	
US-A- 2117071	10/05/38	NONE	
US-A- 2844351	22/07/58	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)